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FILED UNDER SEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PLAINTIFFS UNDER SEAL	)	Civil Action No. 10-2039
	)	
v.	)	**FILED UNDER SEAL**
	)	
DEFENDANTS UNDER SEAL	)	**JURY TRIAL DEMANDED**

THIRD AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* MAX H. WEATHERSBY, JR. and MK LITIGATION PARTNERSHIP 2011, LLP, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, Plaintiffs, v. ENDO PHARMACEUTICALS, INC., ENDO PHARMACEUTICALS HOLDINGS, INC., and JAMES R. HAILEY. Defendants.	Civil Action No. 10-2039 **FILED UNDER SEAL** **JURY TRIAL DEMANDED**

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THIRD AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by Max H. Weathersby, Jr. and MK LITIGATION PARTNERSHIP 2011, LLP (collectively "Relators"), by and through their attorneys, against Defendants Endo Pharmaceuticals, Inc. ("Endo"), Endo Pharmaceuticals Holdings, Inc., and James R. "Rusty" Hailey (collectively, "Defendants") pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*, and pursuant to the *qui tam* provisions of the following States: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.*(2010); the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.* (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.* (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.* (2000); the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.* (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (2006); the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.* (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (2007); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.* (2006); the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 *et seq.* (LexisNexis 2010); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.* (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.* (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.* (2007); the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*

(West 2007); the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.* (McKinney 2010); the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2011); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.* (2007) ("State *Qui Tam* statutes" or "*Qui Tam* States").

I. SUMMARY

1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees or co-conspirators under the False Claims Act and the State *qui tam* statutes.

2. Defendant Endo is a drug maker that has, since at least January 2007, been under investigation by the Federal Government for alleged off-label promotion of its pharmaceutical products, including Lidoderm®. Facing the real possibility that it may be subject to substantial civil penalties and criminal fines, yet needing to maintain the profitability of its cash cow product, which generated over sixty percent of its annual revenues, Endo was presented with a dilemma of how to maintain its lofty sales revenue goals while at the same time operating under the watchful eye of Federal investigators. Endo ultimately elected to embark on an illegal scheme to maintain its revenue goals through a stealth off-label promotion campaign.

3. Endo has successfully maximized its profits through bribes and the illegal, off-label promotion of its pharmaceutical products, including principally Lidoderm®.

4. Since at least July 2006, Endo has purposefully instructed its sales force to illegally promote the off-label use of its drugs, including but not limited to Lidoderm®, for indications not approved by the Food and Drug Administration ("FDA").

5. As part of its plan to expand use of the drug beyond that single indication, however, Endo has sponsored myriad clinical studies, in the hope that one of them would yield positive results sufficient to support additional FDA-approved indications. But none has, and thus Endo has not applied to the FDA to expand its approval of Lidoderm® beyond its lone indication—to relieve the pain of post-herpetic neuralgia ("PHN"). Significantly, for purposes of this Third Amended Complaint, a number of clinically-rigorous Endo trials produced *negative* outcomes (e.g., for the treatment of neuropathic pain, low back pain, chronic axial low back pain, and carpal tunnel disorder) that Endo suppressed in order to facilitate its Fraudulent Marketing Scheme. Further, while hiding these negative results, Endo trained its sales force to use and distribute other marginal, ostensibly favorable studies as part of its off-label scheme. Thus, Endo has falsely promoted Lidoderm® for the treatment of general neuropathic pain, low back pain, chronic axial low back pain, and carpal tunnel disorder despite the fact that its own clinically rigorous studies demonstrated it showed no efficacy (in comparison to a placebo, no less) for these uses.

6. Endo also sought to avoid the prohibition on off-label marketing of its drug products (and the scrutiny of Federal Government investigators) by engaging in an illegal sampling scheme in which it instructed its sales force to encourage off-label sales and use of Lidoderm® by delivering large amounts of free samples to health care professionals, including

for example rheumatologists, who did not treat—and were not likely to treat—patients suffering from the single, narrow condition for which the drug has been approved by the FDA.

7. Though Lidoderm® is only approved by the FDA to treat PHN—a rare form of nerve pain caused by shingles—Endo nevertheless intentionally delivered free samples of the drug to health care professionals who do not treat PHN, but who do treat *other* pain conditions. As described below, Endo expected that these health care professionals would use the Lidoderm® samples to treat their patients suffering from those other off-label conditions. Endo knew that many of these patients were Federal Program beneficiaries, and it intended that their off-label prescriptions would be reimbursed by Federal Programs such as Medicare Part D.

8. Defendants have also engaged in a separate scheme, since at least early 2006, to systematically and illegally provide free samples of Lidoderm® to Defendant Hailey (delivered to his mother) in return for preferential treatment of Endo's drugs on formularies for Coventry Health Care, Inc. and, later, HealthSpring, Inc. These formularies were developed, managed, and controlled by Defendant Hailey, who was their pharmacy director. (On October 24, 2011, Cigna Corporation announced that it had acquired HealthSpring for $3.8 billion.) The purpose and effect of Endo's decision to deliver these free drugs to Hailey's mother, at his request, was to secure favored formulary status for Endo's drugs in order to influence prescribing and utilization decisions, and thereby cause claims for reimbursement to be presented to Government Programs.

9. Defendants have, *inter alia*, knowingly (i) disregarded federal laws and FDA regulations relating to prohibitions on sampling, illegal kickback schemes and off-label promotion; (ii) deliberately concealed, both from physicians and from its own sales representatives, evidence from clinically-rigorous studies showing that Lidoderm® is not effective in the treatment of various off-label conditions; (iii) improperly targeted physicians

who do not treat PHN; (iv) concealed the fact that shipments of free Lidoderm® samples were illegally being traded for preferential formulary treatment; (v) improperly provided kickbacks to a pharmaceutical executive in order to secure Lidoderm®'s status as a preferred drug and thereby fraudulently increase the number of prescriptions written by physicians and, ultimately, the number of reimbursements made to the Defendants by Federal Programs; and (vi) engaged in the off-label promotion of Lidoderm®.

10. Moreover, from at least as early as 2006, the Endo Defendants have failed to accurately report either their Average Manufacturer Price ("AMP") or their Best Price for Lidoderm®, as is required by the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, *et seq.* and their Rebate Agreement(s) with the Secretary of the Department of Health and Human Services. As a result, the Medicaid Program and United States Public Health Service have been deprived of the lowest price on Lidoderm®, i.e., the free goods price the Endo Defendants provided in order to induce preferential formulary treatment. The United States and the *Qui Tam* States have therefore been cheated by Endo out of hundreds of millions of dollars.

11. Defendants thus have violated the Federal Anti-Kickback Act, the Federal False Claims Act, the Federal Prescription Drug Marketing Act and/or the Medicaid Drug Rebate Program and related Rebate Agreement(s), and in so doing they have cheated the Federal Government and the *Qui Tam* States out of hundreds of millions of dollars that should not have been paid, thereby unjustly enriching *all* Defendants.

II. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331 and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws

for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

13. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this District, and engaged in wrongdoing in this District.

14. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

15. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendants to conceal from the United States their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. RELATOR MAX H. WEATHERSBY, JR.

16. Relator Max H. Weathersby, Jr. ("Relator Weathersby") is a resident of Mississippi. He received an Associate of Arts degree in Police Science from Hinds Junior College in 1985, a Bachelor of Science in Administration of Justice from Mississippi College in 1987, and a Master's of Science in Business Management from Belhaven University in 2010. Relator Weathersby was employed by Defendant Endo from July 2006 through September 2010 as a pharmaceutical sales representative with responsibility for the Mississippi region and other areas of the Southeastern United States. Prior to joining Endo, Relator Weathersby worked approximately two years as a pharmaceutical sales representative for Pan American Laboratories. Prior to that, Relator Weathersby spent over sixteen years as an Agent and Agent-In-Charge with the Mississippi Alcoholic Beverage Control Division—the law enforcement branch of the Mississippi State Tax Commission.

17. Relator Weathersby held the title of sales representative throughout his tenure with Endo. As such, his primary assigned role was to call on health care professionals within his assigned region, and to encourage them to prescribe his assigned drugs, including Lidoderm® and OPANA® ER, for their patients. Relator Weathersby's compensation package was calculated as base compensation plus a bonus calculated based on progress toward reaching a predetermined goal for monthly sales growth. In this way, Endo ties compensation for its sales representatives to the Company's sales growth, and it incentivizes each sales representative to increase sales growth irrespective of the rules against kickbacks and off-label marketing.

18. Relator Weathersby is an original source of the kickback, off-label promotion and Medicaid Best Price allegations in this Third Amended Complaint, and these allegations are not based upon publicly disclosed information. He has provided the government with material information prior to the filing of this Third Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2). Also prior to filing this Third Amended Complaint, Relator Weathersby brought the wrongdoing described herein to the attention of Endo.

B. RELATOR MK LITIGATION PARTNERSHIP 2011, LLP

19. Relator MK LITIGATION PARTNERSHIP 2011, LLP is a Delaware general partnership that brings this action on behalf of itself, the United States of America and the *Qui Tam* States named herein. The two partners/owners of the partnership are Relator Weathersby and "Partner B."

20. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, MK LITIGATION PARTNERSHIP 2011, LLP is not distinct from its partners, who have personal knowledge of the aforesaid false claims, statements, concealments, and receipts.

21. The two partners/owners of MK LITIGATION PARTNERSHIP 2011, LLP possess extensive personal knowledge and experience regarding Endo's sales promotion activities, including personal contact with the employees and executives of Endo who have committed the violations of law alleged herein. Relator Weathersby's background and experience is described above. Partner B has been employed by Endo as a pharmaceutical sales representative since 2006, and he has extensive personal knowledge and experience regarding Defendants' sales promotion activities, including personal contact with the employees and executives who have committed violations of law alleged herein. Partner B has observed numerous instances of illegal conduct by the Defendants, including off-label promotion of Lidoderm®.

22. Relator Weathersby and Partner B are original sources of the kickback, off-label promotion, and Medicaid Best Price allegations in this Third Amended Complaint, and these allegations are not based upon publicly disclosed information. They provided the government with material information prior to the filing of this Third Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2), including thousands of pages of documents.

C. DEFENDANTS ENDO PHARMACEUTICALS, INC. AND ENDO PHARMACEUTICALS HOLDINGS, INC.

23. Defendant Endo Pharmaceuticals, Inc. ("Endo"), formerly Endo Laboratories, LLC, is a wholly owned subsidiary of Defendant Endo Pharmaceuticals Holdings, Inc. ("Endo Holdings"). Endo is a Delaware corporation with its principal place of business located at 100 Endo Boulevard, Chadds Ford, Pennsylvania. Endo, which employs more than 1,200 employees throughout the United States, manufactures and markets prescription drug products for sale and use throughout the United States, including in this judicial district.

24. Endo markets numerous analgesic drug products, including Lidoderm® (lidocaine patch 5%) and OPANA® ER (oxymorphone hydrochloride), which are the subject of this Third Amended Complaint.

25. In November 1998, Endo obtained exclusive United States marketing rights to Hind Health Care, Inc.'s Lidoderm®, a patch medication approved by the FDA on March 19, 1999 to treat post-herpetic neuralgia ("PHN"), a nerve pain caused by shingles. Endo also maintained an option to sell Lidoderm® exclusively in Canada and Mexico. Under the terms of the licensing agreement, Lidoderm® is manufactured for Endo by Teikoku Seiyaku Co., Ltd.

26. Endo was the original sponsor of OPANA® ER, which was approved by the FDA on June 22, 2006 for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

D. DEFENDANT JAMES R. "RUSTY" HAILEY

27. Defendant James R. "Rusty" Hailey obtained his Bachelor of Science in Pharmacy from the University of Mississippi School of Pharmacy and his Post-Baccalaureate Doctor of Pharmacy degree from the College of Pharmacy, Albuquerque, New Mexico. Defendant Hailey received his Masters in Business Administration (with an emphasis in marketing) from St. Joseph's University, Philadelphia, Pennsylvania. He holds a Doctor of Pharmacy license in Tennessee and is also licensed to practice Pharmacy in Mississippi.

28. Beginning in 1994, Defendant Hailey was employed by Coventry Health Care, Inc. ("Coventry"), where he served in various roles, including Chief Pharmacy Officer and Senior Vice President of Pharmacy Services, as well as Executive Vice President for Coventry Prescription Management Services. At Coventry, Defendant Hailey oversaw corporate pharmacy strategies, clinical pharmacy initiatives, formulary management, contracting with pharmaceutical

companies, specialty pharmaceuticals, national pharmacy network contracting, pharmacy benefit designs and all aspects of pharmacy practice for Coventry.

29. Defendant Hailey also served as a Corporate Officer of Coventry Health Care, Inc. and as a member of Coventry Health Care's Senior Management team. Defendant Hailey was a Corporate Officer and Board member for Coventry Prescription Management Services, Inc.

30. While at Coventry, Defendant Hailey had full corporate responsibility for Coventry Health Care's Pharmacy Services covering over 6 million lives in all 50 States and Puerto Rico.

31. Dr. Hailey worked with Coventry's sales and marketing and corporate communications department to develop and implement all communications and educational materials related to Coventry Health Care's Pharmacy strategies and programs. He also worked with finance, actuarial and underwriting concerning budgets, benefit designs, RFPs and all pharmacy financial initiatives

32. In late April 2009, Defendant Hailey left Coventry to become Senior Vice President and President of Pharmaceutical Operations for HealthSpring, Inc. ("HealthSpring"). In his current position, Defendant Hailey is tasked with overseeing all of HealthSpring's Medicare Part D operations, including its national stand-alone Prescription Drug Plan.

33. As described more fully herein, Defendant Endo is engaged in the development, manufacture, promotion, distribution and sale of pharmaceutical and health care products throughout the United States. Throughout the relevant period, Endo marketed and sold substantial quantities of its pharmaceutical products, including Lidoderm®, in the Commonwealth of Pennsylvania and in the United States.

34. Defendant Endo conspired with Defendant Hailey, in his capacity as pharmacy director at both managed care companies, to provide free Lidoderm® samples in return for preferential brand treatment of certain Endo drug products on Coventry and HealthSpring's formularies—formularies that are accessible across the United States and that are reimbursed by Federal and State Programs.

35. Defendant Endo markets and sells brand-name prescription drug products, including Lidoderm®, that are paid or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association ("BCBSA"), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq*. via Medicare Part C, (also known as Medicare+Choice), Medicare Part D, Medicare Advantage, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE") and the Veteran's Health Administration ("VHA") (collectively, the "Federal Programs").

36. As a result of Defendants' actions, the *Qui Tam* States and Federal Programs have suffered significant financial harm.

IV. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

A. THE PURPOSE OF THE FRAUDULENT KICKBACK SCHEME

37. It was the plan and purpose of Endo's fraudulent kickback scheme to illegally exchange free Endo drug samples, beginning at least as early as 2006 and continuing to the present, for preferred treatment on Coventry's and HealthSpring's formularies (hereinafter, the

"Fraudulent Kickback Scheme"). These actions constitute violations of the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b), in that they were taken to induce Defendant Hailey, in his capacity as Chief Pharmaceuticals Officer for Coventry and later HealthSpring, to grant Endo drug products favorable categorization as a preferred brand drug. This scheme was orchestrated, at least in part, by Hailey, who directed Endo to provide the free samples in return for the favorable inclusion on Hailey's companies' formularies—formularies that Hailey developed, controlled and managed.

38. The exchange of free drug samples for preferential formulary treatment of Endo's drugs also violates the Prescription Drug Marketing Act of 1987 (the "PDMA"), which prohibits the sale, purchase or trade of drug samples.

39. These kickbacks were intended to result in the dispensing of Defendant Endo's drugs, including but not limited to Lidoderm® and OPANA® ER, and subsequent reimbursement by Endo's customers, including its Government plan customers.

40. The payment and receipt of these kickbacks resulted in increased expense to Government plan customers in as much as Endo's brand name products were more expensive than the cheaper generic equivalents.

41. Endo's provision of free drug samples to Hailey was made knowingly and with the intent to induce Government plan payments for Endo's drug products through a pattern of corrupt and illegal conduct, in violation of the AKA, the PDMA, and the federal and state False Claims Acts.

B. THE PURPOSE OF THE FRAUDULENT MARKETING SCHEME

42. Defendant Endo carried out its fraudulent marketing scheme by engaging its sales force in the illegal, off-label promotion of its drugs, including Lidoderm®, by (i) illegally

promoting Lidoderm® as being effective not just for the treatment of PHN, but for the treatment of all forms of neuropathic pain; (ii) deliberately concealing, both from physicians and from its own sales representatives, evidence from clinically-rigorous studies showing that Lidoderm® is not effective in the treatment of various off-label conditions; (iii) illegally promoting Lidoderm® as being part of a "polypharmacy" treatment regimen; (iv) making fraudulent and unsubstantiated superiority claims regarding Lidoderm® as compared to competitor products; and (v) illegally sampling the drug to health care providers (collectively, the "Fraudulent Marketing Scheme").

43. Endo instructed its sales force to provide large quantities of free samples of Lidoderm® to physicians who Endo knew would not prescribe the drug for on-label, FDA-approved indications. Instead, Endo expected and intended that the physicians would provide the samples for off-label use, and then write off-label prescriptions for the drug that would be reimbursed by Federal Programs, including Medicare Part D.

44. Additionally, Endo trained and directed its sales representatives to use other illegal kickbacks, including exorbitant speaker fees, "Doctor-For-A-Day" programs, and call lists targeting physicians and health care professions who did not treat PHN, to increase sales of Lidoderm® by promoting its use beyond the singular FDA-approved indication.

45. By training its sales representatives to market these drugs for the treatment of indications not approved by the FDA, Endo's illegal, off-label promotion scheme ultimately caused false and fraudulent statements to be made, and caused false and fraudulent claims to be submitted for payment by Federal Programs. This is precisely what Endo had intended. The underlying purpose of the scheme was to maximize Endo's profits. This illegal, off-label

promotion scheme is made in violation of the federal False Claims Act, 31 U.S.C. § 3729 and its state analogues.

C. THE MANNER AND MEANS OF EXECUTING THE SCHEMES

46. Endo utilized its substantial sales force to illegally promote the off-label sales and use of its drugs, including Lidoderm® in order to obtain reimbursement for non-medically accepted indications and other off-label treatments, and thereby maximize profits through false and fraudulent statements to the public, health care professionals and the FDA.

47. For example, Endo routinely and intentionally: (i) distributed substantial quantities of Lidoderm® samples across the country, including to health care professionals Endo knew did not treat patients with PHN, for the sole purpose of increasing sales through off-label use of the drug; (ii) promoted Lidoderm® to health care professionals who did not typically treat patients suffering from PHN—the only condition for which the drug is FDA-approved; (iii) initiated discussions with and among health care professionals about off-label uses of Lidoderm®; (iv) encouraged health care professionals to prescribe Lidoderm® without a proper diagnosis and for uses that are not FDA-approved; (v) trained health care professionals how to evade plan limitations on prescriptions written for off-label purposes to ensure an easier reimbursement process; and (vi) provided health care professionals with false and misleading information regarding the safety and efficacy of Lidoderm®, usually through unapproved studies.

48. It further was part of the schemes that Endo paid illegal kickbacks, beginning at least as early as 2006, in the form of free Lidoderm® samples provided to Hailey's mother, Shirley Bufford. At the time, Hailey was pharmacy director for Coventry (he later assumed a similar role at HealthSpring in 2009). The free samples were provided in exchange for preferential treatment of Endo's drug products on Coventry's (and later HealthSpring's)

formularies. This *quid pro quo* was intended to (and did) induce Hailey to grant Endo's drug products with preferred brand name status on formularies provided to Medicare Part D and Medicaid beneficiaries.

49. It further was part of the Fraudulent Marketing Scheme that Endo attempted to conceal and cover up the off-label marketing of Lidoderm®. All Defendants attempted to conceal the payment of illegal inducements in the Fraudulent Kickback Scheme by directing employees to conceal evidence.

50. Defendant Endo's unlawful off-label promotion of Lidoderm® and its payment of illegal kickbacks involved the unlawful making of a false record or statement and/or causing a false claim to be submitted for the purpose of getting the false record or statement to bring about the Federal government and *Qui Tam* States' payment of a false or fraudulent claim.

51. Each Defendant's conduct had a material effect on the governments' decision to pay for Endo's drug products. Had the Federal Government and *Qui Tam* States known that the preferred brand name status enjoyed by the Endo drug products, or the off-label prescriptions, were the direct and intended result of each Defendant's unlawful activities, they would not have made such reimbursements.

52. Defendants' perpetration of the Fraudulent Marketing and Fraudulent Kickback Schemes is ongoing.

V. BACKGROUND OF DRUGS PROMOTED BY ENDO

A. LIDODERM® (LIDOCAINE PATCH 5%)

53. Lidoderm® was first approved by the FDA on March 19, 1999 for the treatment of pain in post-herpetic neuralgia ("PHN"). Despite the relatively few patients diagnosed with PHN, Endo has aggressively promoted Lidoderm® for indications not approved by the FDA.

54. PHN is a neuralgia caused by the varicella zoster virus. Typically, the neuralgia is confined to a dermatomic area of the skin and follows an outbreak of herpes zoster (HZ, commonly known as shingles) in that same dermatomic area. The neuralgia typically begins when the HZ vesicles have crusted over and begun to heal, but it can begin in the absence of HZ, in which case zoster sine herpete is presumed. In the United States each year approximately 1,000,000 individuals develop herpes zoster. Of those individuals, approximately twenty percent, or 200,000 individuals, develop PHN.

55. There are numerous treatment options for PHN. Options include antiviral agents, analgesics (e.g., locally applied topical agents and lidocaine skin patches like Lidoderm®), systemically delivered treatment (e.g., non-opiates such as paracetamol or the non-steroidal anti-inflammatory drugs), opioids, pain modification therapy (e.g., antidepressants such as serotonin and norepinephrine), and anticonvulsants (e.g., carbamazepin, gabapentin and pregabalin).

56. Although Lidoderm® had a relatively limited on-label PHN market, Endo successfully grew its sales in the off-label pain market. From 2003 to 2008, Lidoderm® achieved more than $3.4 billion in U.S. sales. The U.S. sales of Lidoderm® have been steadily increasing since 2003. In 2008 alone, Lidoderm® attained sales of nearly $1 billion, an increase of twenty percent over 2007. Between the first quarter of 2002 and the third quarter of 2009, Medicaid reimbursements for Lidoderm® totaled more than $838 million, covering more than five million prescriptions.

B. OPANA® ER (OXYMORPHONE HYDROCHLORIDE)

57. OPANA® ER was approved by the FDA on June 22, 2006 for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

58. In 2006, Endo predicted that OPANA® and OPANA® ER would have sales of $20 million to $30 million. *See* http://www.medicalnewstoday.com/articles/45874.php. In 2008, however, OPANA® ER earned $155,662,000 in U.S. sales alone. Between the first quarter of 2007 and the third quarter of 2009, OPANA® ER received more than $20 million in Medicaid reimbursements, covering nearly two million prescriptions.

VI. BACKGROUND OF THE REGULATORY FRAMEWORK

A. THE FOOD AND DRUG ADMINISTRATION REGULATORY SYSTEM

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

59. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

60. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

61. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical

trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

62. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

63. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998. *See, e.g.*, Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979). FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report

suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different endpoints, to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

64. In other cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval—generally only in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

65. Cases in which the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multicenter trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

66. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements About a Drug's Use.

67. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels—including all marketing and promotional materials relating to the drug—may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

68. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks

as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

69. A manufacturer, like Endo, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

70. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, e.g., treating a child when the drug is approved to treat adults.

71. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians

also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug Company sponsored continuing medical education ("CME") courses and speaker programs, and drug Company sponsored clinical trials.

72. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. § 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

73. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described below.

74. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use

that are not approved or permitted in the drug package labeling." *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

75. The FDA regulations that fall under the general rubric of 21 C.F.R. § 202.1(e)(6) *et seq.* ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Endo may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Federal Programs, including Medicaid.

76. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. § 202.1(e)(6)(iv).

77. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. § 202.1(e)(5) *et seq.* A Company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

78. Section 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

79. Section 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

80. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

81. Section 99.101 *et seq.* lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." *Id.* § 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. *Id.* § 99.101(b)(2).

82. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

83. And off-label information may be disseminated only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

84. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body—the FDA. And the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA Has Limited Authority To Regulate Drug Maker Marketing and Promotion.

85. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

86. DDMAC's effectiveness in regulating off-label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if at all, only after the materials already

have appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the Company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

87. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

88. The FDA's ineffectiveness in policing off-label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf. Among the Report's findings: (1) FDA does not have separate oversight activities to specifically capture off-label promotion; (2) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (3) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (4) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives; (5) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

B. PRESCRIPTION DRUG PAYMENT UNDER FEDERAL HEALTH CARE AND OTHER PROGRAMS

89. Whether an FDA-approved drug is approved for a particular indication (i.e., use) determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program, the Medicaid Drug Rebate Program and the 340B Drug Pricing Program

90. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

91. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

92. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6). During the time period relevant to this Third Amended Complaint, Endo promoted off-label uses of Lidoderm® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug compendia specified by the Medicaid statute.

93. Between the third quarter of 1999 and the third quarter of 2009 (the last period for which such data is publicly available), Medicaid reimbursements for Lidoderm® has totaled almost $850 million, covering more than one million prescriptions.

94. In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs and determined that Medicaid routinely was paying more than other large drug purchasers for prescription drugs, particularly for "single source drugs" (i.e., drugs, like Lidoderm®, that were protected by patents). *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress further found that, in order to contain skyrocketing drug costs, State Medicaid programs were denying beneficiaries access to needed medications. *See* 136 Cong. Rec. S12954-01, *S12955 (Sept. 12, 1990). Congress concluded that "Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." 1990 U.S.C.C.A.N. at 2108. Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Id.*

95. Congress enacted the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 1990"). Pursuant to the Medicaid Drug Rebate Program, participating manufacturers that want their drugs covered by Medicaid must contract with the federal government in a manner that is consistent with Congressional intent. A drug manufacturer thus must enter into a Rebate Agreement with the Secretary of the Department of Health and Human Services ("HHS") in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs, 42 U.S.C. § 1396r-8(a)(1). Each participating manufacturer must sign, indicating agreement and

compliance with all provisions therein, including that "[t]he Rebate Agreement shall be construed in accordance with federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." *Id.* A sample agreement is available at https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf.

96. The Rebate Agreement provides that the Secretary enters the agreement "on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement)." Upon entering into a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating State based on all of the manufacturer's drugs purchased by that State pursuant to its Medicaid plan during that quarter.

97. Drug manufacturers are required under the Medicaid Drug Rebate Program and the Rebate Agreement to calculate and report their average manufacturer prices ("AMPs") and best prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(b)(3)(A)(i); Rebate Agreement at § II(e). Any information provided by a manufacturer or wholesaler under the Medicaid Drug Rebate Program is confidential and "shall not be disclosed by the Secretary . . . or a State agency . . . except as the Secretary determines to be necessary to carry out this section." 42 U.S.C. § 1396r-8(b)(3)(D); Rebate Agreement at § VII.

98. Pursuant to the Rebate Agreement, "the Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized."

99. In addition, "Best Price" means "with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated

payments), in the same quarter for which the AMP is computed." "Best Price" is "inclusive of cash discounts, free goods, volume discounts, and rebates. . . ." Pursuant to the Rebate Agreement, a manufacturer is obligated to adjust the best price "if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized."

100. The Rebate Agreement provides that, in the absence of guidance, a manufacturer may make reasonable assumptions in calculating its Best Price, but that those assumptions must be consistent with the Medicaid Drug Rebate Program statute and Rebate Agreement, and *must be documented in either a written or electronic record. See* Rebate Agreement at § II(i).

101. The Rebate Agreement further provides that any ambiguities "shall be interpreted in the manner which best effectuates the statutory scheme," and that "nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law." *See* Rebate Agreement at § IX(e), (d).

102. The information provided by the manufacturer under the Rebate Agreement must be complete and accurate. Pursuant to the OBRA 1990 statute and Section 1927(b)(3)(C)(ii) of the Social Security Act, the Secretary of HHS may impose penalties of up to $100,000 for each item of false information provided by a manufacturer.

103. States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty days after the end of the rebate quarter. *See* 42 U.S.C. § 1396r-8(b)(2)(A). Using the manufacturer pricing data, the Centers for Medicare and Medicaid Services ("CMS", formerly "HCFA") division of HHS computes the unit rebate amount ("URA") "to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due." *See* Rebate Agreement at § I(dd). Using the

Medicaid drug utilization data, manufacturers calculate and pay the States the rebates they believe are due and owing to each State.

104. In 1992, Congress enacted Section 340B of the Public Health Service Act, known as the "340B Program," to provide drug price protection for certain PHS entities that receive federal funds. *See* 42 U.S.C. § 256b. PHS entities include such safety net programs as black lung clinics, State operated AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, and disproportionate share hospitals, all as further defined in the Drug Pricing Program. *See* 42 U.S.C. § 256b(a)(4).

105. Under the 340B Program, drug manufacturers are required to enter into an agreement with HHS with nearly identical obligations as under the Rebate Agreement, and to agree that the amount required to be paid (taking into account any rebate or discount) by the 340B Program entities for covered drugs would not exceed the average manufacturer price, as reported to CMS under the Medicaid Drug Rebate Program in the previous calendar quarter, minus a specified rebate percentage. *See* 42 U.S.C. § 256b(a)(1). For each covered outpatient drug, the rebate percentage is to be equal to the average rebate required under the Medicaid Drug Rebate Program during the preceding calendar quarter, divided by the average manufacturer price for the drug during such quarter. *See* 42 U.S.C. § 256b(a)(2).

2. The Medicare Program

106. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

107. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

108. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

109. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

110. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.

111. During the time period relevant to this Third Amended Complaint, Endo promoted off-label uses of Lidoderm® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug compendia specified by the statute.

3. Reimbursement Under Other Federal Health Care Programs

112. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs. For example:

(i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.

(ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100% service-connected disabilities.

(iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

113. During the time period relevant to this Third Amended Complaint, Endo promoted off-label uses of Lidoderm® that were not eligible for reimbursement under any of the various federal health care programs.

VII. FDA AND COMPENDIUM APPROVAL OF LIDODERM®

A. FDA APPROVAL OF LIDODERM®

114. While the FDA approved Lidoderm® only for the treatment of PHN, Endo has aggressively sought to expand the indications for the drug. For example, Endo hoped to expand its label by sponsoring studies for indications to test the effectiveness of Lidoderm® in the treatment of various conditions, including osteoarthritis of the knee, carpal tunnel syndrome, and low back pain. However, to date, none of these studies has yielded a positive result, and many of the results indicate no effectiveness at all. One study concluded that the *placebo group* demonstrated greater improvement in alleviating lower back pain than did the subjects using Lidoderm®. Examples of these failed studies include:

(i) In a comparison of the efficacy and safety of Lidoderm® with a placebo in patients suffering from osteoarthritis of the knee, a study found there was no statistically significant difference for the primary endpoint (efficacy), and the secondary endpoint (safety) did not yield results that could be measured using the traditional pain endpoints selected for the study. *A Randomized, Double-Blind, Pilot Study Comparing the Efficacy and*

Safety of Lidocaine 5% Patch With Placebo in Patients With Pain From Osteoarthritis of the Knee, EN3260-001 (last updated Feb. 9, 2010).

(ii) An Endo-sponsored concurrent study in which it compared Lidoderm® to Celebrex® (celecoxib) early in patients suffering from osteoarthritis of the knee was terminated early after safety concerns arose regarding the Celebrex® class of drugs (though the secondary endpoint (safety) showed that use of the drug for up to 12 weeks in patients with pain from osteoarthritis was well tolerated and safe). *A Randomized, Open-Label Study Comparing the Efficacy and Safety of Lidocaine Patch 5% With Celecoxib 200 mg in Patients With Pain From Osteoarthritis of the Knee*, EN3220-012 (last updated Feb. 12, 2010).

(iii) In its attempt to garner support for an indication in the treatment of lower back pain, Endo sponsored a study of the efficacy and safety of Lidoderm® with a placebo. However, the study found there was no statistically significant difference between the two treatment groups for either the primary endpoint (efficacy) or the secondary endpoint (safety). *A Randomized, Double-Blind Study Comparing the Efficacy and Safety of Lidocaine 5% Patch With Celecoxib 200 mg in Patients With Chronic Axial Low Back Pain*, EN3261-001 (last updated Feb. 9, 2010).

(iv) Endo attempted a head-to-head study with Celebrex® (celecoxib) in patients suffering from chronic axial low back pain. The study was halted because Vioxx® (rofecoxib) was withdrawn from the market prior to the completion of enrollment. No conclusions were drawn on the secondary

endpoint (safety) due to incomplete data collected. *A Randomized, Open-Label Study Comparing the Efficacy and Safety of Lidocaine 5% Patch With Celecoxib 200mg in Patients With Chronic Axial Low Back Pain*, EN3220-013 (last updated Feb. 12, 2010).

(v) As part of its attempt to secure a new indication in the treatment of carpal tunnel syndrome, Endo commissioned a study comparing the efficacy and safety of Lidoderm® with a placebo. The study was terminated before an efficacy analysis was possible, and there was no statistically significant difference for the secondary endpoint (safety) of the study. *A Randomized, Double-Blind Study Comparing the Safety and Efficacy of Lidocaine 5% Patch With Placebo in Patients With Pain From Carpal Tunnel Syndrome*, EN3272-301 (last updated Feb. 12, 2010).

(vi) In another head-to-head study, the efficacy and safety of Lidoderm® monotherapy was compared to Neurontin® (gabapentin) monotherapy in patients with peripheral neuropathic pain. The comparative efficacy yielded no statistically significance between the two treatment groups, while the treatment was found to be moderately safe. *A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Of Lidocaine Patch 5% Alone, Gabapentin Alone, And Lidocaine Patch 5% And Gabapentin In Combination For The Relief Of Pain In Patients With Diverse Peripheral Neuropathic Pain Conditions*, EN3220-009 (last updated Feb. 12, 2010).

(vii) Finally, in a study designed to evaluate the analgesic efficacy of Lidoderm® compared to a placebo in patients with moderate to severe chronic low back pain, the placebo group actually demonstrated a greater improvement in average daily pain intensity from the baseline week to the final week, while the secondary endpoint (safety) yielded marginally positive results. *A Prospective, Double-Blind, Randomized, Placebo-Controlled Pilot Study of the Efficacy and Safety of Lidocaine Patch in the Treatment of Low Back Pain*, EN3220-011 (last updated Feb. 12, 2010).

115. In all, Endo has commissioned at least 187 studies since 1999 to test the efficacy and safety of Lidoderm® for off-label indications. Of those studies, only seven (7) have produced results of any kind, and, as discussed *infra* ¶¶ 192-213 at least three of the studies (those denoted as EN3220-009, EN3220-011 and EN3261-001) produced *negative* results demonstrating that Lidoderm® is either not effective for the studied use or no more effective than the placebo. It merits emphasis that none of these Lidoderm® studies sponsored by Endo has ever been published in the medical literature—further evidence that while Endo has been aggressive in its off-label efforts to promote Lidoderm®, it will take equally aggressive measures to cover up any negative studies that reflect poorly on the off-label uses of the drug.

116. Not surprisingly, Endo has been the recipient of two DDMAC Warning Letters from the FDA. On November 24, 1999, DDMAC informed Endo that its marketing claim that seventy-eight percent of patients preferred Lidoderm® versus a placebo patch failed to divulge that the results promoted by Endo could not be generalized to the entire population. DDMAC notified Endo that the "efficacy claims [were] misleading because they disclose favorable

conclusions from a study, in the absence of qualifying contextual information concerning the study's limitations."

117. On June 28, 2005, Endo received another Warning Letter from DDMAC, this time ordering Endo to immediately cease distributing misleading promotional materials that violated FDA rules and regulations. The Warning Letter explained that the advertising materials were "false and misleading because they make unsubstantiated effectiveness claims for Lidoderm, they omit and minimize serious risk information associated with use of the drug, and they inadequately communicate an important limitation in Lidoderm's indication." Endo had failed to inform users that Lidoderm® "should be applied only to intact skin." By failing to adequately communicate Lidoderm®'s approved indication, the advertisements failed to caution against unsafe use of the product, including application to broken or inflamed skin.

B. COMPENDIUM APPROVAL OF LIDODERM®

118. Congress has adopted a compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." *See* Social Security Act §§ 1927(g)(1)(B)(i) and (k)(6). The statute permits reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."

119. Thus, the only way a prescription for an off-label use can be reimbursed under Medicaid, Medicare or the other Federal Programs is if the particular off-label use has been approved by one of the compendia identified in the Social Security Act, such approval qualifying the use as a "medically accepted indication."

120. In both the leading and most commonly available statutorily approved compendium, DrugDex and the American Hospital Formulary Service-Drug Information ("AHFS") there are currently are no compendia-supported off-label uses for Lidoderm®.

C. REPORTED SERIOUS ADVERSE EVENTS IN THE CONNECTION WITH THE USE OF LIDODERM®

121. There have been numerous reported adverse events associated with the use of Lidoderm®, including reported deaths. According to DrugLib.com, twenty-seven adverse events were reported in connection with the use of Lidoderm® between April 2009 and August 2010. *See Lidoderm® (Lidocaine Patch)—Side Effects & Adverse Reactions Reported to FDA*, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/lidoderm/ (last visited Sept. 20, 2011). Of those twenty-seven reported events, twenty-one were categorized as "resulting in a serious event," of which nine were categorized as "resulting in death." Recurring reactions include reports of cardiac arrest, drug ineffectiveness, vomiting, pruritus (itching), and somnolence.

122. Four of the nine reported deaths involved incidents in which the only reported "suspect drug" administered to the patients was Lidoderm®. *See Lidoderm® (Lidocaine Patch)—Adverse Event Reports—All Cases—Death*, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/lidoderm/seriousness_any/reaction_death/ (last visited Sept. 20, 2011). Specifically, on February 3, 2010, a pharmacist submitted an adverse event report to the FDA explaining that a forty-nine-year-old male patient and a forty-three-year-old female patient both died. The only reported "suspect drug" was Lidoderm®. Previously, in November 2009, the FDA received at least two additional adverse event reports from physicians who reported that patients died under similar circumstances.

123. These adverse events show that Endo's nationwide campaign to promote Lidoderm® for uses not approved by the FDA has had potentially serious consequences that directly implicate patient health.

VIII. THE FRAUDULENT KICKBACK SCHEME

A. ENDO PAYS ILLEGAL KICKBACKS TO DEFENDANT HAILEY TO INDUCE HIM TO GRANT PREFERRED BRAND STATUS FOR ENDO'S DRUGS, THEREBY OPENING THE DOOR TO IMPROPER FEDERAL PROGRAM REIMBURSEMENTS

124. Many health care organizations, such as hospitals, institutional pharmacies, state Medicaid agencies, and managed care organizations, maintain lists of preferred drugs that can be prescribed by health care professionals within that organization, or that are eligible for reimbursement by that organization. These lists are commonly called "formularies." The Pharmacy and Therapeutics ("P&T") Committee of a health care organization decides which pharmaceutical products are included on the formulary.

125. Defendant Hailey served on the P&T Committees for Coventry Health through April 2009, and thereafter at HealthSpring, and he held prominent and influential positions with each health plan as its pharmacy director. From 1994 until April 2009, Defendant Hailey served Coventry in various senior management roles, including most notably Chief Pharmacy Officer and Senior Vice President of Coventry's Pharmacy Services. Coventry, whose operations focus primarily on Federal Programs, maintains a Medicare Advantage line of business that, as of December 31, 2009, covered 515,000 members and accounted for $4.9 billion of revenue in 2009. Revenue from Coventry's Private Fee-For-Service products made up $2.9 billion of that total. Coventry's Medicare Part D business accounted for $1.5 billion of revenue in 2009 and was responsible for 1.7 million members as of December 31, 2009. Coventry also offers health care coverage to Medicaid recipients in six states which, as of December 31, 2009, covered

402,000 members and accounted for $1.1 billion of revenue in 2009. Specifically, Coventry received 8.4%, 10.3%, and 10.7% of its managed care premiums for the years ending December 31, 2009, 2008 and 2007, respectively, from its state-sponsored Medicaid programs throughout its various health plan markets.

126. In April 2009, Defendant Hailey left his position at Coventry and took a similar position at HealthSpring, Inc. as its Senior Vice President and President of Pharmaceutical Operations, where his responsibilities involve overseeing all of HealthSpring's Medicare Part D operations, including its national stand-alone Prescription Drug Plan. HealthSpring, similar to Coventry, is a managed care organization whose primary focus is handling patients covered by Medicare Advantage and other Federal Programs. As of December 31, 2009, HealthSpring coordinated Medicare Advantage plans in Alabama, Florida, Illinois, Mississippi, Tennessee, and Texas. Beginning January 1, 2010, HealthSpring also commenced operations of Medicare Advantage plans in three counties in Northern Georgia. As of December 31, 2009, HealthSpring's Medicare Advantage plans had over 189,000 members. In 2009, HealthSpring collected Medicare Advantage premiums of $2.3 billion, reflecting an increase of 22.5% over the prior year. Approximately 20.6% of HealthSpring's 2009 revenue was attributable to Medicare Part D premiums, up from 14.7% in 2006, the first year of Part D's implementation.

127. P&T Committees for managed care organizations like Coventry and HealthSpring typically make formulary decisions based upon assessments of safety, efficacy, tolerability, and—increasingly—cost-effectiveness. In some cases, organizations with P&T Committees may be acting on behalf of Medicaid, Medicare Part D, or other Government health care programs. Members of P&T Committees are expected to avoid both actual and apparent conflicts of interest when making formulary decisions.

128. At all times material hereto, Coventry was one of the largest Medicare/Medicaid contractors in the United States. As of December 31, 2008, Coventry's Medicare Advantage line of business covered 380,000 members in all 50 states, the District of Columbia, and Puerto Rico; its Medicare Part D business had 931,000 members; and it offered health care coverage to Medicaid recipients in eight states (primarily in Florida, Michigan, and Missouri), which covered 371,000 members. All of these Coventry plans offered prescription drug benefits through a formulary of drugs selected by its P&T Committee, which had been headed by Defendant Hailey.

129. At all times material hereto, HealthSpring was one of the largest Medicare/Medicaid contractors in the United States. As of December 31, 2009, HealthSpring's operated coordinated care Medicare Advantage plans had over 189,000 members in Alabama, Florida, Illinois, Mississippi, Tennessee, and Texas; its Medicare Part D business had 313,000 members, substantially all of whom were dual eligible Medicare/Medicaid beneficiaries. All of these HealthSpring plans offered prescription drug benefits through a formulary of drugs selected by its P&T Committee, which had been headed by Defendant Hailey.

130. At all times material hereto, as part of the Fraudulent Kickback Scheme, Endo actively sought to buy influence through Hailey so that he would add Endo's products to the Coventry and HealthSpring formularies (both very large and influential Medicare and Medicaid HMOs), and thereby influence prescribing and utilization decisions on Medicare and Medicaid claims for beneficiaries across the country. As part of its Scheme, Endo provided illegal kickbacks to Defendant Hailey in order to influence his decision to include Lidoderm® and other Endo products on Federal Program formularies, and thereby influence prescribing and utilization decisions on Medicare and Medicaid claims for beneficiaries throughout the United States.

B. ENDO MANIPULATED ITS RELATIONSHIP WITH DEFENDANT HAILEY TO SECURE PREFERRED FORMULARY STATUS OF ITS DRUGS

131. In order to increase sales, and profits, Endo planned and implemented the Fraudulent Kickback Scheme to induce Government Programs to provide favorable treatment for its drugs, including Lidoderm®.

132. Specifically, Endo schemed to provide free samples of Lidoderm® to Defendant Hailey's mother, at Hailey's specific request, with the understanding that Hailey, in his capacity as pharmacy director for Coventry and later HealthSpring, would use his influence to secure Endo's drugs with preferred brand status on each managed care Company's formulary, thereby influencing prescribing and utilization decisions by physicians for Medicare and Medicaid beneficiaries throughout the United States. This provision of free Lidoderm® in exchange for favorable formulary status was a violation of the federal Anti-Kickback Act ("AKA").

133. Emails among Endo employees reveal the basic nature of Endo's fraudulent kickback scheme. For example, in December 2007, Stephen Musial, Senior Corporate Account Executive for Endo, asked Desiree Smith, an Endo District Sales Manager, who among the sales representatives might be available to assist him by providing free samples of Lidoderm® to Dr. James Polk, the treating physician for Defendant Hailey's mother. The email is set forth below:

From: Musial, Steve
Sent: Wednesday, December 19, 2007 5:11 PM
To: Smith, Desiree
Subject: Dr. Polk, Richland, Mississippi

Desiree,

I am hoping you can help me with one of our customers. Dr. Rusty Hailey's mother takes Lidoderm. Dr. Hailey is the senior VP of Coventry Corporation and Endo has enjoyed a solid working relationship with the company over the past five years. Amy Adams has helped me in the past and would have Max Weathersby leave some samples at Dr. Hailey's mother's physician, Dr. James Polk, in Richland Mississippi.

If you could verify that this Dr. Polk is still in Max's area and that he could leave some boxes with Dr. Polk and place a note that they are for Dr. Rusty Hailey's mother, Shirley Bufford, it would be a great help.

Dr. Hailey states that his Mom has probably sold more Lidoderm in Mississippi than many of our representatives and the product has helped her tremendously.

Thanks so much for helping me out with this; it just goes a long way to do a little extra for a client's family member who is in need of one of our products.

If you could get back to me, I would also like to send the representative a thank you note and a copy of a note that Dr. Hailey's mother wrote me the last time.

Sincerely,

Steve Musial

134. In this email, Mr. Musial described a "solid working relationship" since 2002 that was created through illegal remuneration—the provision of free Lidoderm® drug samples to Hailey's mother—in order to influence Hailey's conduct as pharmacy director for Coventry. The email demonstrates that Endo's purpose and intent in providing free drug samples to Hailey's mother was to induce Hailey to grant preferential treatment for Endo's drugs on Coventry's formulary, for which payment may be made in whole or in part under Federal Programs.

135. The not-so-subtle message among Hailey, Musial, and Smith was that, in exchange for Endo's delivery of free Lidoderm® samples to Hailey's mother, Hailey would reciprocate by ensuring that Endo's drugs would enjoy favorable formulary status. And,

favorable formulary status meant increased Endo sales, including to Federal Program participants.

136. Just a few days later, Mr. Musial contacted Relator Weathersby, and asked for his assistance in delivering the free samples. Musial wrote:

From: Musial, Steve
Sent: Wed 12/26/2007 12:06 PM
To: Weathersby, Max
Subject: Dr. Polk, Richland MS

Max,

Do you still have Dr. James Polk in Richland, MS? Dr .Rusty Hailey who is the Senior VP for Coventry Healthcare would like for us to drop Dr. Polk some Lidoderm samples off for his mother, Shirley Bufford.

Dr. Hailey has been an extreme advocate for Lidoderm and Opana ER over the past several years. You may have done this for me in early 2006; Shirley Bufford wrote me a personal thank you letter and invited me for dinner. If you can leave some boxes with her name on it with Dr. Polk and/or inform me what representative has him in their territory I would appreciate it so much. Here is a couple "thanks" for you or the rep to help us out.

Thanks so much,

Steve Musial

NAE

St. Louis

137. Musial had agreed to provide free Lidoderm® for Hailey's mother in exchange for Hailey's advocacy for Lidoderm® and OPANA® ER. Musial's email also made clear that Hailey was personally involved in the kickback scheme, as he was actively engaged in promoting Endo's drugs at Coventry in his role as pharmacy director. Endo senior executives thus knew that Hailey was in a position to influence the formulary status of Endo's drugs, and that preferred formulary status would lead to increased sales, as well as increased reimbursements by Federal Programs.

138. For his part, Hailey knew that it was improper to exchange influence for free drug samples, but he knew that he was in a position to influence the formulary status of Endo's drugs, and he sought the bribe nonetheless.

139. Nor was this a one-time occurrence. Instead, similar communications occurred several times over the next few years. In January 2009, for example, Smith told Relator Weathersby during a phone call, that Musial needed another case of samples to be dropped off at Dr. Polk's office for Mrs. Bufford. Relator Weathersby told Smith that, because Mrs. Bufford's son was a doctor, one would think that Hailey would buy her medicine. Smith just laughed off the suggestion and informed Relator Weathersby that "we just do what we have to do." Relator Weathersby told Smith that Endo needed to start sending him extra Lidoderm® samples if he was going to have to keep dropping off large quantities for Mrs. Bufford. Smith ensured Relator Weathersby that she would get him the extra samples necessary to accommodate Mrs. Bufford.

140. As these examples demonstrate, Musial and/or Smith would direct that cases of Lidoderm® samples be delivered free of charge to Hailey's mother, and each time Hailey and/or his mother extended their thanks personally. And, as the emails and phone calls further reflect, this had been a multi-year effort to trade free drug products in order to curry improper influence over Coventry's (and later HealthSpring's) formularies.

141. The ongoing scheme to bribe Defendant Hailey succeeded. In 2008, OPANA® ER appeared on Coventry Health Care's Preferred Drug List Formulary for the first time, and both Lidoderm® and OPANA® ER were listed as preferred brand name drugs in 2009. In fact, Lidoderm® moved from not being on formulary at all to a preferred position as a Tier II drug. OPANA® ER was also made a Tier II drug.

142. Endo knew that its kickback scheme was illegal. In its own guidance documents, Endo explains the AKA and the type of conduct the law is designed to prevent. For example, Endo acknowledges in its Health Care Compliance Guide (Revised May 2009) that the law "applies to relationships with all our customers, including health care professionals, managed care entities and hospitals." The same Guide (including the version that was given to Relator Weathersby as part of his initial training with the Company in 2006) explains that, while the Company's policy against violating the Anti-Kickback Act does not prohibit Endo from promoting its products, it nevertheless "places certain parameters around *how* and *why* we provide certain things of value (such as meals or gifts) to our customers" (emphasis in 2006 original).

143. These kickbacks were intended to increase sales of Endo's drugs generally, as well as Federal Program reimbursements in particular, since Endo knew that Hailey was the key decision-maker for a number of large government Medicaid and Medicare formularies. Endo knew and intended that buying Hailey's loyalty would result in increased sales of Lidoderm® and OPANA® ER on these government health plans. The bribes did improperly and illegally influence Hailey's selection of Lidoderm® for inclusion on formularies provided to government programs in violation of the AKA, 42 U.S.C. § 1320a-7b(b).

144. The Endo managers and employees involved in the Fraudulent Marketing Scheme were fully aware that it was against Endo policy, and also illegal, to provide free Lidoderm® samples in exchange for favorable treatment of Endo's products on the formularies controlled by Defendant Hailey. Endo's Compliance Code, which all Endo employees are required to sign an acknowledgement that they have read and agree to abide by, explicitly prohibits providing an inducement to an Endo customer with the intent to influence that person to recommend or

purchase a health care product that may be reimbursed by a federal health care program. In addition, Endo employees are prohibited from providing anything to a customer in exchange for any implicit or explicit agreement or understanding to use, purchase, order, recommend, prescribe or dispense any Endo product. Nonetheless, in flagrant violation of Endo's own stated policies, these managers and employees engaged in the practice anyway because they understood that the Company's first priority was to promote its products, not comply with the law.

145. Endo's payment of, or offer to pay, kickbacks, and the receipt of kickbacks by Hailey, were made knowingly and with the intent to induce Government Program payments through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729.

146. The Defendants thus knowingly and willfully offered, paid, and received illegal remuneration in violation of the AKA, 42 U.S.C. § 1320a-7b(h)(2). But for the illegal kickbacks, Government Programs would not have paid for the prescription claims tainted by these kickbacks.

147. As a result of these kickbacks, Government Programs have suffered significant damages.

IX. ENDO VIOLATED ITS OBLIGATIONS UNDER THE MEDICAID DRUG REBATE PROGRAM, ITS REBATE AGREEMENT(S) WITH HHS, AND THE FEDERAL 340B PROGRAM.

148. As described above, Endo's Fraudulent Kickback Scheme resulted in the provision of multiple, large volume free doses of Lidoderm® to Defendant Hailey, which were delivered to his mother, Shirley Bufford. These were not "samples" provided to educate Ms. Bufford or her physician on whether Lidoderm® would be beneficial to her care, as contemplated by the Prescription Drug Marketing Act (*see* discussion *infra*), nor were they provided so that

she could simply "try out" Lidoderm®. Instead, Endo delivered to her substantial *maintenance* volumes of Lidoderm®, at Hailey's specific request, in the same quantities otherwise available only through commercial channels, as a *quid pro quo* for Hailey's conduct in ensuring favorable treatment for *multiple* Endo drug products, including both Lidoderm® and OPANA ER®, on the HealthSpring and Coventry formularies and thereby influencing prescribing or utilization decisions. Endo and Hailey knew that such favorable treatment would lead to greater numbers of prescriptions for those drugs, including prescriptions for Government Program beneficiaries, throughout the United States.

149. Neither Ms. Bufford, nor Dr. Polk, nor Defendant Hailey were ever billed or invoiced for these products.

150. At all material times, Endo knew that a substantial number of prescriptions written by physicians for Coventry and HealthSpring plan participants were written as a result of Endo's Fraudulent Kickback Scheme and would be reimbursed by the Medicaid program and/or 340B entities.

A. ENDO REPORTED FALSE "BEST PRICES" FOR LIDODERM®

151. Endo has entered into one or more Rebate Agreements with the Secretary of HHS pursuant to the OBRA 1990 Statute and the Medicaid Drug Rebate Program. That Endo has entered into one or more such agreements is confirmed by the fact that it has been issued two Medicaid Pharmacy Rebate Program Labeler Codes: 60951 and 63481. Endo also has entered into one or more agreements to participate in the 340B Program, described *supra*.

152. Thus, Endo has since the inception of its first Rebate Agreement been required to accurately report to CMS both its Average Manufacturer Price ("AMP") and its Best Price for Lidoderm®. *See* discussion *supra*.

153. AMP is to be calculated as "Net Sales divided by the number of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)." *See* Medicaid Sample Rebate Agreement available at https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf.

154. Best Price is to be calculated "inclusive of cash discounts, free goods, volume discounts, and rebates." *See* Medicaid Sample Rebate Agreement, available at https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf. Thus, Endo was obligated to report the "free goods" described herein.

155. The free Lidoderm® that Endo provided to Hailey's mother should have been included in Endo's reported Best Price for Lidoderm® because it provided the drugs free of charge contingent on Hailey's conduct in ensuring preferred formulary status for Endo's drug products, thereby causing greater numbers of prescriptions to be written for those products throughout the United States. *See* 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(l)(C). Section 1927(c)(1)(C)(ii)(I) of the Social Security Act specifies that the reported Best Price must include free goods that are contingent on *any* purchase requirement.

156. The Best Prices for Lidoderm® that Endo did report during the term of its Rebate Agreement(s) were false because they wrongfully omitted the free drugs that were delivered to Hailey's mother and were contingent on Hailey's conduct in delivering additional prescriptions for Endo's drug products.

B. THE UNITED STATES AND *QUI TAM* STATES WERE CHEATED OUT OF SUBSTANTIAL SUMS AS A RESULT OF ENDO'S FALSE REPORTS

157. Because Endo intentionally reported false Best Prices for Lidoderm®, it wrongfully failed to pay accurate quarterly rebates to each State during each applicable rebate

period. And, consequently, Endo wrongfully over-charged Section 340B Program participants for Lidoderm®, and it retained such overpayments.

158. Medicaid's reimbursements of Lidoderm® during the period in which Endo was providing free Lidoderm® to Hailey's mother were substantial. Relators do not know precisely when Endo began providing free Lidoderm® to Hailey's mother, as Mr. Musial's email indicates that Relator Weathersby was not the first sales representative to be instructed to make such deliveries. However, between the first quarter of 2002 and the third quarter of 2009, Medicaid programs paid more than $838 million for Lidoderm®, and unit prices ranged from $4.16 to $6.59 (excluding three outlier quarters where the data seems to be incorrect, e.g., Q1 and Q2 2006 and Q3 2007). Specifically:

Year and Quarter	Units Reimbursed	Total Amount Reimbursed	Unit Price
2002/1	939925.09	$3,905,689.29	$4.16
2002/2	1228712.16	$5,193,022.28	$4.23
2002/3	1591317.1	$6,767,168.37	$4.25
2002/4	2043953	$8,671,231.93	$4.24
2003/1	2433597.34	$10,320,513.84	$4.24
2003/2	2815365	$12,197,066.08	$4.33
2003/3	3288685.248	$14,632,370.53	$4.45
2003/4	4066445	$18,061,788.43	$4.44
2004/1	4622047.754	$20,922,976.61	$4.53
2004/2	5570245.1	$27,001,627.01	$4.85
2004/3	5807529.04	$28,222,155.14	$4.86

2004/4	7138002.365	$34,654,604.74	$4.85
2005/1	7692319.44	$39,706,755.49	$5.16
2005/2	8697704.229	$45,223,744.10	$5.20
2005/3	8962584.6	$47,151,481.12	$5.26
2005/4	9623689.04	$58,047,831.21	$6.03
2006/1	4589249.73	$60,951,151.76	$13.28
2006/2	4138347.14	$65,155,398.61	$15.74
2006/3	4185594.62	$23,583,167.03	$5.63
2006/4	4382953.2	$25,361,455.87	$5.79
2007/1	4266995	$24,715,077.63	$5.79
2007/2	4230021.82	$24,533,430.26	$5.80
2007/3	4287675.86	$42,482,677.11	$9.91
2007/4	4361933.231	$26,628,413.73	$6.10
2008/1	4466188.45	$27,318,678.51	$6.12
2008/2	4623299.75	$29,012,472.57	$6.28
2008/3	4187769.588	$26,281,649.47	$6.28
2008/4	3557535.442	$22,339,482.02	$6.28
2009/1	3075601	$20,029,647.26	$6.51
2009/2	3218663.66	$21,202,544.48	$6.59
2009/3	2762972.4	$18,188,430.72	$6.58

159. Medicaid did not receive the Best Price (i.e., the "free goods" price) that Endo was providing to Mr. Hailey for the benefit of his mother.

160. Endo knowingly (or with reckless disregard for the truth) made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Specifically, for the period noted above, and continuing through the present, Endo knowingly (or in reckless disregard of the truth) submitted false quarterly statements to CMS of its Best Prices on Lidoderm® to reduce improperly its rebate obligation to the States under the Best Price Program.

161. Endo's false quarterly statements of its Best Prices caused the States to submit false and inflated submissions to the Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2).

162. Under its Rebate Agreement(s) with the Secretary of HHS, Endo was required to certify its compliance with applicable law, including the Medicaid Drug Rebate program. Endo's knowing failure to comply renders its certifications false, either expressly or impliedly.

163. By virtue of the false or fraudulent claims that Endo knowingly caused to be presented, the United States and the *Qui Tam* States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

164. The false reports of Best Price by Endo trigger liability under the False Claims Act and its state counterparts. Under the Best Price statute, Endo was to report its truthful prices to the Secretary, who in turn reported these prices to the states, who then invoiced Endo the amount of Best Price rebates that were owing. Under the False Claims Act and the State *Qui Tam* counterparts, Endo is liable even if it did not make a false statement itself directly to the state "Medicaid agency," so long as a direct or indirect result of their conduct was causing a false statement to be made to the state Medicaid agency.

165. Because Endo knowingly, and in reckless disregard for the truth, made false reports of Best Price to the Secretary, the "unit rebate amounts" or "URAs," which represent the products of calculations performed on AMPs and Best Prices which were Endo's responsibility to report, also were false. As such, (i) Endo knowingly, and/or in reckless disregard for the truth, made, used, or caused to be used Best Price or AMP statements or records made to CMS to conceal, avoid, or decrease an obligation to the United States; (ii) the statements or records were false; and (iii) Endo knew that the statements or records were false.

166. By virtue of the false or fraudulent claims that Endo knowingly caused to be presented, the United States and the *Qui Tam* States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

X. THE FRAUDULENT MARKETING SCHEME

A. ENDO TRAINED ITS SALES REPRESENTATIVES TO PROMOTE LIDODERM® FOR OFF-LABEL USES

167. From the time it launched Lidoderm® in 1999, Endo used written training materials to instruct its sales representatives how to promote off-label uses of Lidoderm®. These materials make clear that Endo expected its sales representatives to: (i) illegally portray Lidoderm® as being effective not just for PHN, but for all forms of neuropathic pain even though Lidoderm® has only been approved for the treatment of PHN; (ii) illegally promote Lidoderm® as part of a "polypharmacy" treatment regimen, i.e., using a number of different drugs as part of combination therapy, even though Lidoderm® had no such FDA approvals; and (iii) fraudulently misrepresent efficacy and safety features of Lidoderm® as compared to competitor products by using clinical studies with completely different trial designs and inclusion criteria to create the false impression that Lidoderm® had "prevailed" in head-to-head studies.

1. Endo Trained Its Sales Representatives To Promote Lidoderm® Illegally For All Forms of Neuropathic Pain

168. From the launch forward, Endo provided its sales representatives with training materials that touted Lidoderm® as the appropriate treatment not only for its specific, FDA-approved indication, PHN, but also for all forms of neuropathic pain (which the FDA has never approved).

169. Neuropathic pain is a broad label that includes a diversity of causes and mechanisms. Accordingly, the FDA has refused to grant approval to any drug for the treatment of neuropathic pain *generally*, even though the drug may be effective in treating one particular neuropathic pain condition. Instead, the FDA has required that a drug demonstrate effectiveness in treating each individual neuropathic pain condition for which its manufacturer seeks approval. This requirement is based on the FDA's recognition that a drug may be effective for treating one neuropathic pain condition, but not another. Endo has ignored this important limitation.

170. For example, in a 2006 new-hire training manual, Endo sales representatives including both Relator Weathersby and Partner B were taught that "the five first-line pharmacologic options for ***neuropathic pain*** are opioids, the 5% lidocaine patch [Lidoderm®], gabapentin, [tricyclic antidepressants], and tramadol hydrochloride." (Emphasis added). The manual states that clinical studies support the use of Lidoderm® as first-line therapy to relieve ***neuropathic pain***. The manual further explains that Lidoderm® and other drugs "have been demonstrated to effectively relieve ***neuropathic pain*** in multiple randomized, controlled clinical trials of various conditions." (Emphasis added). While the manual later recognizes that Lidoderm® is only approved by the FDA to treat PHN, it oversteps that boundary in the very next sentence by falsely concluding that, because an off-label clinical study had shown that all five

drugs demonstrated similar results regardless of the class of neuropathic pain treated, "it is reasonable to assume that each drug [including Lidoderm®] may work in a variety of patients."

171. As part of this training, sales representatives including Relator Weathersby and Partner B were taught to, and did, practice delivering off-label neuropathic pain details in which they did not even mention PHN, but instead promoted Lidoderm® for the treatment of all forms of neuropathic generally. Thus, Endo trained its sales representatives from the outset to promote Lidoderm® for all forms of neuropathic pain.

172. Endo's former National Sales Training Manager, Nicole Tarantello, specifically taught Partner B that if a physician tells him that she does not treat PHN, Partner B should ask whether she treats neuropathic pain instead, and to then promote Lidoderm® for that broader purpose.

173. More recently, Endo has instructed its sales representatives to utilize the so-called "Binder Study" (which examined the effectiveness of Lidoderm® *only* for the treatment of PHN) as a key tool to promote sales for the treatment of ***neuropathic pain generally***, *see* discussion *infra* ¶¶ 246-53, even though the Company's own trials have shown that Lidoderm® is no more effective than placebo for these uses, *see* discussion *infra* ¶¶ 192-213.

174. By training its sales representatives to expand the use of Lidoderm® from its FDA-approved indication for PHN only to all forms of neuropathic pain, Endo senior management actively and illegally promoted the drug for off-label purposes.

2. Endo's Executive Management Actively Encourages the Off-Label Promotion of Lidoderm®

175. Not only were sales representatives trained to promote the use of Lidoderm® for the treatment of neuropathic pain generally, this was actively condoned and encouraged by senior Endo executives.

176. Partner B is considered by Endo to be a star within the sales force. Thus, in 2008 he was awarded the Company's "Rising Sun Award"—a national honor based on sales, leadership and "team player" qualities as they relate specifically to the promotion of Lidoderm®. Further, he was invited to join Chief Operating Officer Nancy Wysenski on a trip to Japan in March 2008 and then to "shadow" her for several days upon their return to the United States. Thereafter, COO Wysenski joined Partner B for a field ride on August 19, 2008, during which she observed him promote several Endo drugs, including Lidoderm®, to several physicians, including Drs. Yousef Zibdie and Dr. Mohammad Ibrahim of West Patterson, New Jersey.

177. Neither Dr. Zibdie nor Dr. Ibrahim treated any patients who suffered from PHN, but Partner B followed his training and proactively promoted Lidoderm® to both physicians as an ideal treatment for ***neuropathic pain generally***. Pursuant to his training, Partner B opened his sales details to Drs. Zibdie and Ibrahim by asking: "Doctor, when it comes to areas of localized pain—deep, stabbing, burning pain—what guidelines do you follow and what products do you consider?" Partner B then led these doctors into a discussion of the off-label use of Lidoderm® for the treatment of ***neuropathic pain generally*** and provided each with twenty free Lidoderm® sample patches (even though neither physician requested any samples).

178. COO Wysenski observed these plainly off-label sales pitches, and even though they were unprompted and thus illegal, she neither stopped Partner B nor criticized him after they had concluded their physician visits. Instead, Wysenski praised Partner B for what she considered to be excellent promotional practices. In fact, the day after the ride-along, COO Wysenski sent Partner B an email with the subject line "Enjoyed the day!", in which she thanked him for allowing her to "understand what a day in the field looks like at Endo." She explained further that, as a result, she developed a "much better sense for how we approach our physicians

at Endo." And, rather than reprimanding or correcting Partner B regarding the proactive, off-label message she observed him deliver during their ride-along, Wysenski instead declared him to be "an impressive sales person who easily models years of skill development."

179. Wysenski's complicity in the blatant off-label promotion of Lidoderm® reflects the larger culture of corruption at Endo that has sustained a longstanding and nationwide fraudulent marketing scheme. Knowing that only a small percentage of physicians actually treat PHN, Endo's senior management has systematically trained, directed and, as with COO Wysenski, actually encouraged its sales representatives to promote the drug for uses beyond its lone approved indication in the Company's drive to realize nearly $1 billion in annual sales.

3. Endo Trains Its Sales Representatives To Promote Lidoderm® Illegally As Part of a "Polypharmacy" Treatment Regimen

180. In furtherance of the Fraudulent Marketing Scheme, Endo's training materials also educate its sales representatives on the competitive advantages of combining Lidoderm® with different drugs to treat certain conditions—an approach that Endo refers to as "polypharmacy." Endo's off-label promotion of this type of such combination therapy is not approved by the FDA, nor is it supported by any of the compendia.

181. For example, promotional materials from 2007 encourage sales representatives to promote polypharmacy by touting Lidoderm® "as the foundation of PHN treatment—alone or in combination with systemic analgesics." Endo quotes Dr. Dennis J. Patin MD, Chief of Anesthesiology and Pain Management at the University of Miami Hospital, as stating that Lidoderm® "is the foundation of my rational polypharmacy approach."

182. Endo's illegal polypharmacy promotion continues today. In its 2010 Lidoderm® Master Visual Aid, Endo still promotes the drug for use in combination therapy. Under the heading "Key Messages," sales representatives are instructed to inform health care providers that

Lidoderm® "is recommended for PHN pain by respected third parties—alone or with oral analgesics." Similarly, a sales aid Endo provided to its sales representatives on July 6, 2010 contains messaging for high prescribers to use Lidoderm® "as a first-line therapy for PHN, either alone or with oral analgesics."

183. Insofar as the FDA has never approved Lidoderm® in combination with any other drug for the treatment of PHN, these materials illegally promote the off-label use of Lidoderm®.

4. Endo Makes Fraudulent, Unsubstantiated Superiority Claims for Lidoderm®

184. A key part of the Fraudulent Marketing Scheme has been Endo's positioning of Lidoderm® as superior to competing products without adequate, well-controlled studies to support such claims. At all times material hereto, Endo has trained its sales representatives to promote Lidoderm® by making improper superiority claims about its efficacy and safety as compared to other products, including Neurontin®, Lyrica®, Celebrex® and Cymbalta®. These superiority claims are made despite the absence of adequate, well-controlled, head-to-head studies comparing Lidoderm® with any of the other drugs.

185. Before it will approve a drug for a specific indication, the FDA requires that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations." 21 C.F.R. § 314. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. According to the FDA's 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness."

186. As a result of the FDA's clear policy requiring "substantial evidence" to support marketing claims, a drug maker may not make comparative efficacy claims to physicians by simply comparing product inserts (a product's approved labeling), nor may a drug maker's

promotion to physicians compare two non-comparative trials (due to differences in trial designs, inclusion criteria and other factors).

187. As an example of its flagrant violations of FDA's clearly-stated policy against making superiority claims, Endo's 2006 new hire training manual armed sales representatives with background information on competing products to assist them in making the Company's superiority claims. One section included background on Neurontin® (gabapentin), an oral medication approved by the FDA to treat both PHN and epilepsy. In discussing the advantages and disadvantages of Neurontin® as compared to Lidoderm®, the manual accurately acknowledges that "Neurontin® and LIDODERM® patch have not been compared in head-to-head trials." But it then reverses course and brazenly instructs representatives how they should tout Lidoderm®'s superiority: "taken separately, however, data from trials for the two drugs do not suggest that Neurontin® would provide superior pain relief for PHN patients compared to LIDODERM® patch."

188. Endo also provides its sales representatives with promotional materials containing clinical reprints and peer reviews that, on their face, support the use of Lidoderm® for the treatment of PHN. A closer examination, however, reveals that these materials are intended to mislead health care providers about Lidoderm®'s efficacy as compared to competing drugs (absent the requisite head-to-head studies).

189. For example, promotional materials published in 2007 contain a "practice parameter" reprint that holds itself out as detailing head-to-head comparisons of Lidoderm® with numerous others drugs for the treatment of PHN, including the anxiety drug Ativan® (lorazepam), the cough suppressant dextromethorphan, and acupuncture. Concluding that Lidoderm® showed more favorable results than the majority of these other treatments, Endo's

"practice parameter" improperly presents health care professionals with results that are inherently inaccurate and misleading insofar as the treatments' approved indication profiles are different and there are no head-to-head studies that reliably compare them under a single, well-controlled clinical setting.

190. Endo also provides its sales representatives with "Lidoderm Competitor Pocket Summaries," which ostensibly are provided "for sales training purposes only" and are "not to be copied, distributed, or used in sales calls." The competitor drugs in the Pocket Summary include Cymbalta®, Lyrica®, and Celebrex®—despite the fact their FDA-approved indication profiles are nothing like Lidoderm®'s. These other drugs are approved for (i) major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain and fibromyalgia (Cymbalta®); (ii) management of neuropathic pain associated with diabetic peripheral neuropathy, management of postherpetic neuralgia, adjunctive therapy for adult patients with partial onset seizures and management of fibromyalgia (Lyrica®); and (iii) osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, primary dysmenorrhea and familial adenomatous polyposis (Celebrex®). Plainly, their approved uses extend well beyond PHN, and thus there is little to no legitimate basis upon which to compare them against Lidoderm®. That Endo does so is proof of its scheme to promote Lidoderm® for use well beyond its single FDA-approved indication.

191. Despite the fact that there were (and still are) no adequate, well-controlled, head-to-head clinical studies supporting a comparison of Lidoderm® with Neurontin®, Lyrica®, Celebrex® or Cymbalta®, Endo nevertheless trained its sales representatives to promote Lidoderm® as being superior to these other drugs. By including these types of claims in its

training materials for new hires, Endo directs its sales representatives to engage in illegal superiority comparisons that directly contradict FDA regulations.

B. ENDO SUPPRESSED ITS OWN CLINICALLY RIGOROUS STUDIES THAT SHOWED LIDODERM® IS NOT EFFECTIVE FOR THE TREATMENT OF LOW BACK PAIN, CARPAL TUNNEL SYNDROME AND NEUROPATHIC PAIN, IN ORDER TO FACILITATE ITS FRAUDULENT MARKETING SCHEME

192. As discussed *supra*, Lidoderm® is FDA approved only for relief of pain associated with PHN. As part of its plan to expand use of the drug beyond that single indication, Endo has sponsored myriad clinical studies, presumably in the hope that one of them would yield positive results. But none has, and thus Endo has not applied to the FDA to expand its approval of Lidoderm®. Significantly for purposes of this Third Amended Complaint, however, five clinically rigorous Endo trials produced *negative* outcomes that Endo suppressed in order to facilitate its Fraudulent Marketing Scheme.

1. The EN3220-009 Study Showed That Lidoderm® Is No More Effective Than Placebo for the Treatment of Neuropathic Pain Generally

193. In June 2003 (approximately six years before the Binder Study was published), Endo completed a clinically rigorous study that concluded Lidoderm® is no more effective than placebo for the treatment of diverse neuropathic pain conditions. *See Clinical Trial Results Summary: EN3220-009*. The EN3220-009 trial was a multicenter Phase IV trial that was randomized, double-blind and included both placebo- and active-controlled groups.

194. Despite the inclusion of a host of efficacy measures, including four questions on average daily pain assessment, Lidoderm® did not show statistically significant superiority for *any* of those measures. In fact, for two questions on the daily pain questionnaire, patients taking Lidoderm® experienced the *least* amount of improvement of the four groups. In other words, patients taking the placebo fared better than the patients taking Lidoderm®.

195. This study was never published.

2. The EN3220-011 Study Showed that Lidoderm® Is No More Effective Than Placebo for the Treatment of Low Back Pain

196. By August 2003, Endo had completed a Phase IV study that definitively showed that Lidoderm® was no more effective than placebo for the treatment of low back pain. *See Clinical Trial Results Summary: EN3220-011.* Entitled *A Prospective, Double-Blind, Randomized, Placebo-Controlled, Pilot Study of the Efficacy and Safety of Lidoderm® Patch in the Treatment of Low Back Pain,* all available information indicates that the study was well-designed. The EN3220-011 trial was a randomized, double-blind, and placebo-controlled study. Had the results been positive, it likely would have been of sufficiently rigorous quality to support an application to the FDA for a supplemental indication for treatment of low back pain. But the results were not positive.

197. The primary endpoint of the EN3220-011 study was the change in average pain intensity, recorded by patients on a daily basis, from the baseline week to the final week of the study. The results showed that patients on the placebo experienced a *greater* average daily improvement (2.54) than did those on Lidoderm® (1.91). The difference was not considered statistically significant, meaning that the placebo and Lidoderm® were found to be of comparable efficacy for the relief of low back pain.

198. The EN3220-011 study included several secondary endpoints to measure relative efficacy of Lidoderm® versus placebo, and each of those secondary endpoints also showed that there was no statistically significant difference between Lidoderm® and placebo.

199. In sum, the EN3220-011 study provided strong evidence that Lidoderm® is no more effective than placebo for the relief of low back pain.

200. This study was never published.

3. The EN3261-001 Study Showed that Lidoderm® Is No More Effective Than Placebo for the Treatment of Chronic Axial Low Back Pain

201. From August 2004 to October 2005, Endo conducted a Phase II study that was designed to assess the efficacy of Lidoderm® for the treatment of chronic axial low back pain. *See Clinical Trial Results Summary: EN3261-001*. Entitled *A Randomized, Double-Blind Study Comparing the Efficacy and Safety of Lidocaine 5% Patch with Placebo in Patients with Chronic Axial Low Back Pain*, the EN3261-001 study was similar in design to the EN3220-011 study, and thus it, too, bore all the hallmarks of a clinically rigorous study.

202. The primary endpoint of the EN3261-001 study was the change in average daily pain intensity over the course of the study. While both treatment groups experienced an overall decrease in pain, there was no statistically significant difference in change in pain intensity between the Lidoderm® and placebo treatment groups. Thus, once again, a clinically rigorous trial conducted by Endo itself showed that Lidoderm® is no more effective than placebo for the treatment of low back pain.

203. This study was never published.

4. The EN3272-301 Study Showed that Lidoderm® Is No More Effective Than Placebo for the Treatment of Carpal Tunnel Syndrome

204. From November 28, 2005, through January 4, 2007, Endo conducted a study that examined the safety and efficacy of Lidoderm® for treatment of pain from carpal tunnel syndrome ("CTS"). Titled *A Randomized, Double-Blind Study Comparing the Safety and Efficacy of the Lidocaine Patch 5% With Placebo in Patients With Pain From Carpal Tunnel Syndrome, EN3272-301*, the study included 210 patients and sought to determine whether there was a difference in average worst daily pain intensity between the Lidoderm® and placebo treatment groups.

205. However, before reaching its planned conclusion, the study was terminated and the efficacy analysis never completed, following an interim review showing that there was not expected to be a statistically significant difference in efficacy between the placebo and Lidoderm® groups. As conveyed in Endo's summary of the trial, "[t]he results of this blinded interim analysis indicated that the sample size that would be required to show a statistically significant difference between the two treatments [sic] groups was far larger than was initially expected."

206. This comment is particularly surprising, given that the sample size in EN3272-301, which included 210 patients, was actually very large compared to Lidoderm®'s two FDA registration trials, which included only 35 and 32 patients, respectively. That implies two possibilities, or a combination thereof: (1) patients in EN3272-301 experienced a substantially greater variance in pain intensity than did patients in Lidoderm®'s registration trials (all else equal, greater variance within a sample requires a greater sample size in order to reach statistical significance); or (2) patients who received Lidoderm® in EN3272-301 experienced substantially less of an efficacy benefit, relative to patients who received placebo, than did patients in Lidoderm®'s registration trials (all else equal, a smaller observed difference in outcome between treatment groups requires a greater sample size in order to reach statistical significance).

207. The first possibility (that patients in EN3272-301 experienced an unusually great variance in day-to-day pain intensity) appears unlikely, given that other studies that have examined use of corticosteroids to treat carpal tunnel syndrome have routinely demonstrated statistically significant differences in efficacy between treatment groups using sample sizes of between 32 and 60 patients. *See* Girlanda et al., *Local steroid treatment in idiopathic carpal tunnel syndrome: short- and long-term efficacy*, 240 J. NEUROLOGY 187 (1993) (32 patients);

Dammers JWHH et al., *Injection with methylprednisolone proximal to the carpal tunnel: randomized double blind trial*, 319 BRIT. MED. J. 884 (1999) (60 patients); D O'Gradaigh & P Merry, *Corticosteroid injection for the treatment of carpal tunnel syndrome*, 59 ANNALS RHEUMATIC DISEASES 918 (2000) (52 patients). The consistency with which these and other clinical trials have demonstrated statistically significant differences between groups demonstrates that excessive intra-group variance does not preclude achieving statistically significant results using modest patient populations.

208. The more likely explanation, therefore, appears to be the second one: that Endo's expectation that the study, if completed, would fail to demonstrate a statistically significant difference in efficacy between treatment groups, was caused by an observed similarity in outcomes between the treatment groups. That is, Endo realized during its interim analysis that the mean efficacy outcomes in the placebo and Lidoderm® treatment groups were similar, and would likely remain similar at the study's conclusion, thereby precluding a statistically significant finding of Lidoderm®'s superiority.

209. Thus, while Endo's summary of the clinical trial implies that the expected failure to achieve statistical significance was the result of the study's flawed design, the actual explanation appears to be that the expected failure to achieve statistical significance was the result of Lidoderm® being no more effective than placebo for the treatment of CTS.

210. This study was never published.

5. Endo Suppressed the Results of Its Negative Studies in Order to Further Its Fraudulent Marketing Scheme

211. Endo did not publish the results of the EN3220-009 study, the EN3220-011 study, nor the EN3261-001 study, but instead concealed them. Summaries of each study now are

available at the www.clinicaltrials.gov website, but those summaries (which apparently were not available on that website until May 15, 2009) do not include the study results themselves.

212. The results of these studies are available only as PDF summaries that may be downloaded directly from Endo's website. *See Clinical Trial Results Summary: EN3220-009,* www.endo.com/pdf/clinicalTrialDocs/EN3220-009.pdf (last visited Sept. 29, 2011); *Clinical Trial Results Summary: EN3220-011*, www.endo.com/pdf/clinicalTrialDocs/EN3220-011.pdf (last visited Sept. 12, 2011); *Clinical Trial Results Summary: EN3261-001*, www.endo.com/pdf/clinicalTrialDocs/EN3261-001.pdf (last visited Sept. 20, 2011. Locating these summaries requires approximately five clicks from the website's homepage, such that only a user who is expressly looking for the studies' results is likely to find them. (A "Google" search for the term "Lidoderm low back pain" conducted on September 12, 2011 did not locate the results of either study in the first fifteen pages of results.)

213. The metadata associated with the PDF files available on Endo's website indicates that the files associated with the EN3220-011 and EN3261-001 studies were created in December 2009—four years after the EN3261-001 study was completed, and more than six years after the EN3220-009 and EN3220-011 studies were completed. Consistent with the late date on which the trial information apparently was submitted to www.clinicaltrials.gov, this suggests that the studies' results were not made publicly available until well after Relator Weathersby and other Endo sales representatives were directed by Endo to proactively promote Lidoderm® for the treatment of low back pain, and neuropathic pain generally, as discussed herein.

6. Endo's Senior Management Confirm During Investor Earnings Calls that They Suppressed Lidoderm® Clinical Studies

214. Comments made by senior Endo executives during quarterly investor earnings calls repeatedly confirm (1) that Endo sought to achieve sales of Lidoderm® for uses beyond its

FDA-approved indication of treatment of pain associated with PHN; and (2) that Endo actively concealed it already knew that Lidoderm® was not effective for a number of these uses, including for treatment of low back pain. During these earnings calls, Endo's executives repeatedly commented that the Company continued to study the effectiveness of Lidoderm® for these off-label uses in the hope of one day receiving an FDA indication, even though they knew the Company had long since completed studies that conclusively demonstrated Lidoderm® was ***not*** effective for these uses.

215. For example, during the Company's Q1 2004 Earnings Conference Call on April 21, 2004, Carol Ammon, who was then Chairman and CEO of Endo Pharmaceutical Holdings, Inc., discussed the Company's ongoing excitement about clinical studies to expand Lidoderm®'s indications, particularly for treatment of low back pain:

> DAVID BUCK, ANALYST, BUCKINGHAM RESEARCH: Yes, good morning, just a couple of questions. First on Lidoderm®; Carol can you give an update on what near-term programs you may have on R&D? You've mentioned back pain in the past, is there anything that would be presented at the American Pain Society Meeting? . . .
>
> CAROL AMMON: Let me take the Lidoderm® question first. We continue to be excited about this product and we have continued to study this product, done a number of Phase IV [studies]. Possibility of looking at it for utility in a variety of neuropathic pain conditions such as osteoarthritis and chronic low back and a variety of neuropathies. And based upon those we did embark upon a Phase II program for Lidoderm® in chronic low back, so we're currently in a Phase II program. Nothing to report at this time on that, but with a product that's patent protected out through 2015 it really is very worthwhile for us to continue to study the application of the product. And as we get more data on this we will certainly be reporting that at the appropriate time.

See Q1 2004 Earnings Call. While Ammon noted that the Company had conducted a number of Phase IV studies on additional uses of Lidoderm®, she neglected to note that one of those studies (EN3220-011) had shown that Lidoderm® was ***not*** effective for treatment of low back pain.

Instead, she stated that Endo was still interested in that use and was awaiting the results of an ongoing Phase II study (EN3261-001).

216. A year later, on February 10, 2005, Endo's then Chief Science Officer, Dr. David Lee, made similar comments in response to an analyst's question:

> ROBERT UHL, ANALYST, FRIEDMAN, BILLINGS, RAMSEY & COMPANY: Good morning and thank you. Could you just update us on where you are with the additional -- I believe it is chronic back pain studies with Lidoderm® and when might there be an FDA decision there -- I'm sorry, submission.
>
> DR. DAVID LEE: Right, yes. This is a Phase II program that is ongoing and will be running for much of 2005. And in this program, we were really trying to evaluate which was the most appropriate parameters to be studying in an eventual Phase III program, what is the right definition of the patient population, and how do we maximize our chances of demonstrating an effect of Lidoderm® in an indication where we know that there is going to be a large placebo response? So we really do need to see the results of the studies that we have underway, and at that point, we will decide whether we need to do further exploratory studies or that we feel confident enough to go into a Phase III program and look forward to then to an eventual regulatory submission.

See Q4 2004 Endo Pharmaceuticals Earnings Conference Call (emphasis added). Just as Ammon had, Dr. Lee referenced the ongoing Phase II study while omitting any reference to the completed Phase IV study. Lee's omission is particularly curious given that the purpose of the Phase II study, he stated, was to better define the protocol for a future Phase III study. (Phase IIIb studies are frequently referred to interchangeably as Phase IV studies, meaning that Endo had already completed just the study Lee was referencing).

217. On April 21, 2005, Peter Lankau, then President and COO of Endo Pharmaceuticals Holdings, Inc., told investors that the Company was studying Lidoderm® for the treatment of osteoarthritis of the knee and low back pain:

> PETER LANKAU: Thanks, Jeff. As has been mentioned in the first quarter this year we experienced a reduction in inventory levels of Lidoderm® by certain of our customers that was somewhat similar to what happened in the second quarter

> of 2004. I am pleased to note, however, that the underlying prescription demand for Lidoderm® remains strong. We continue to be enthusiastic about the short-term and long-term growth prospects for Lidoderm®.
>
> At the recent American Pain Society Meeting in Boston we presented the results of an open label Phase IV study in osteoarthritis patients that was the first to compare Lidoderm® head-to-head with a Cox-2 inhibitor. In this case, Celebrex. Though the trial was voluntarily halted prior to reaching the original enrollment target, due to the safety concerns around the C[o]x-2 class, the results suggest that Lidoderm® can alleviate the pain associated with osteoarthritis of the knee. And as we are currently engaged in a Phase II program for Lidoderm® in chronic low back pain, we continue to evaluate additional indications for Lidoderm®.

See Q1 2005 Endo Pharmaceuticals Earnings Conference Call (emphasis added). Once again, as had his colleagues on prior calls, Lankau omitted all reference to the completed Phase IV study on low back pain.

218. By July 1, 2005, a few months before completion of its Phase II study on use of Lidoderm® for low back pain, Endo began to temper investor expectations for an expanded indication. Responding to an analyst's inquiry about when the study's results would be available, Dr. Lee stated:

> IAN SANDERSON: Okay, and then finally, just on the two back pain Phase II studies for Lidoderm® and Lidopain, when might we see results or would we see results from those?
>
> DAVID LEE: I can't speak for EpiCept. They are responsible for the Lidopain study, as Peter indicated. They I think have announced that they are anticipating initiating a Phase II-B study in the second half of 2005. Our Lidoderm® study will probably be complete around the turn of the year or the early part of next year. I am not sure whether the results would be material enough for us to announce it will -- but I think depend on what our future strategy may be around the product, so we'll decide later on.

See Q2 2005 Endo Pharmaceuticals Earnings Conference Call (emphasis added). Lee's comment—that he was uncertain whether the Company would announce the Phase II study's results—foreshadows, and is an acknowledgement of, Endo's eventual suppression of the study's negative results.

219. Approximately one year later, on July 20, 2006 (when the Company had completed both the Phase IV and Phase II studies), an analyst specifically asked then President and COO Lankau whether Endo planned on using such data to seek an additional indication, or if it planned to simply supply the data to its sales force—the clear implication being that the sales force could then use the data to promote Lidoderm® off-label. In response, Lankau clearly acknowledged that this data would likely not be sufficient to garner a new FDA indication, but that the Company definitely planned to disseminate it anyway by alternate means:

> DAVID WINDLEY: . . . The questions I have on follow-up are just all kind of sales force related, Peter. . . . The data that you referenced in my earlier question, I'm wondering, strategy on additional indications on Lidoderm®, are you looking for actual label or is your intent more to supply the sales force with data that they can then go out and drop with docs or reference with docs. . . .
>
> PETER LANKAU: With regards to Lidoderm® and the clinical data that we have been generating and will continue to generate. Certainly, we are interested in continuing the lifecycle of Lidoderm® in any way that we can. The data that we have been generating over time has been very useful to continue to articulate for physicians the clinical characteristics of the product. Should we be fortunate enough to find an avenue to pass regulatory muster for an additional indication, that would certainly be very appropriate for us. However, we explore many different options and at this stage, we have not indicated that we have certainly anything imminent or that there was a particular direction that we will sort of bet the ranch on.
>
> So the effect of this is that the additional data sets that we collect and disseminate will be done primarily through continuing medical education programs, publications, posters, conferences, etc. And if published in a peer review journal, could be distributed only under a restricted materials category.

See Q2 2006 Endo Pharmaceuticals Earnings Conference Call (emphasis added).

220. Chief Science Officer Dr. David Lee continued to make comments indicating that research on Lidoderm®'s effectiveness was ongoing. On October 19, 2006, Dr. Lee responded to an analyst's question on the precise issue of low back pain:

> GARY NACHMAN: Are you still doing work on Lidoderm® in low back pain?

> DAVID LEE: We continue to do [exploratory] studies for Lidoderm® in other indications. We've mentioned chronic low back pain, osteoarthritis in the knee, carpal tunnel syndrome. And those we'll continue. We have never given any indication when any results are going to be published. This is not something that we're making a big deal of because these are exploratory studies and we've always said that the outcome of these studies could be that we would want to proceed to a full phase III program, or we may want to do additional exploratory studies or we may just decide that any particular indication is not worth pursuing, perhaps because clinical trial methodologies aren't sensitive enough; we haven't got the right study design and so on. So we'll be continuing to progress those over the next few months.

See Q3 2006 Endo Pharmaceuticals Earnings Conference Call (emphasis added). Yet again, Lee referenced the possibility of conducting a Phase III study in the future, while omitting that a Phase IV study had already been completed.

221. These comments represent a clearly articulated desire by Endo to expand the use of Lidoderm® well beyond its current FDA-approved indication. That desire is echoed in Endo's SEC filings, such as its Form 10-K, filed February 26, 2008:

> While the orphan drug exclusivity period for Lidoderm® has expired, Lidoderm® is currently protected by Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents is set to expire in 2015. In addition, we are currently exploring potential additional indications of Lidoderm® through Phase II safety and efficacy studies.

(emphasis added).

222. While Endo may have initially hoped to expand Lidoderm®'s use by obtaining FDA approvals for supplemental applications, thereby broadening the drug's approved use, President Lankau's comments in particular make clear that the Company was willing to expand Lidoderm®'s use by alternate means—i.e., by illegal, off-label promotion by the Company's sales representatives. In the context of the information provided by Relators, it is clear that these were exactly the alternate means to which Endo would resort.

C. AS IT SUPPRESSED CLINICALLY RIGOROUS STUDIES WITH NEGATIVE RESULTS, ENDO PROMOTED DEMONSTRABLY INFERIOR AND MATERIALLY MISLEADING STUDIES TO SUPPORT OFF-LABEL USE OF LIDODERM®

223. Endo has operated a widespread scheme to promote Lidoderm® for off-label indications for which it knew there was no adequate clinical evidence supporting such use. In fact, Endo used weak open label studies while actively suppressing double blind, placebo-controlled negative clinical studies showing Lidoderm® worked no better than a placebo for these uses. At all times material hereto, Endo knew that it was prohibited by the FDCA from promoting off-label uses of Lidoderm®. Nevertheless, because of the limited population of persons suffering from the single, narrow indication for which Lidoderm® has been approved, Endo has encouraged doctors to prescribe Lidoderm® for off-label uses as well.

224. At nearly every Plan of Action ("POA") meeting that either Relator Weathersby or Partner B attended, sales representatives asked their managers why the Company had not yet received approvals for additional indications beyond PHN. While at first they were told that the Company was conducting research that would support seeking FDA approvals, occasionally managers were more candid. For example, at Partner B's September 21, 2008 POA meeting for his district and the adjoining district, District Manager Wayne Morris candidly answer this question by telling the representatives that the Company did not need to get FDA approvals for additional indications since they were already getting this business.

225. In order to evade government detection, Endo trains its sales representatives to encourage doctors to prescribe Lidoderm® for off-label uses and without confirming a diagnosis of PHN. At the same time, Endo apparently has made no serious effort to provide its sales representatives with ongoing training on how to comply with the federal regulations that prohibit off-label promotion.

226. Instead, Endo has instructed its sales representatives to promote the drug for such other conditions as lower back pain, osteoarthritis, carpal tunnel syndrome, arthritis and other forms of neuropathic pain that Lidoderm® is not FDA-approved to treat. Endo expects that its sales representatives will tell health care professionals that Lidoderm® is a successful therapy for such conditions, and that they will promote Lidoderm® to health care professionals who treat those off-label conditions, but not PHN.

227. Endo's license agreement with has compelled it to maintain a high level of off-label sales. Under the terms of its original 1998 supply and manufacturing agreement with Teikoku Seiyaku Co. Ltd., as well as a 2007 amendment, Endo has a minimum purchase requirement of approximately $32 million per year through 2012.

228. In light of the relatively few patients who are diagnosed with PHN each year, Endo has been under enormous pressure to promote Lidoderm® off-label in order to be able to fund its annual obligation to Teikoku Seiyaku Company and meet its own lofty revenue goals.

229. This pressure to sell Lidoderm® has manifested itself in the directives issued by senior management to the sales force. For example, Desiree Smith, who until recently was a District Sales Manager and Relator Weathersby's direct supervisor, constantly instilled in her sales team the off-label mantra that they should "[l]ead them down that path." What she meant by this was that sales representatives should lead health care professionals down a path to prescribing Lidoderm® off-label. Thus, she instructed her representatives first to explain to physicians what neuropathic pain is, and then to explain that PHN is a serious kind of neuropathic pain. The "path" that she described is one on which health care professionals will "learn" that if Lidoderm® is appropriate for PHN, which is the most severe form of neuropathic pain, then it is appropriate not simply for all forms of neuropathic pain, but for *any* kind of pain.

This illegal promotion seeks to expand the off-label market for Lidoderm® well beyond the lone indication approved by the FDA.

230. This same "lead them down the path" message recently was conveyed to Partner B by Manhattan District Manager Wayne Morris at a POA meeting in Weehawken, New Jersey on September 12-14, 2011.

1. Endo Uses the Gammaitoni and Gimbel Trials to Promote Lidoderm® for the Off-Label Treatment of Low Back Pain

231. In May 2004 (nine months after Endo had completed the last patient visit for the EN3220-011 study), Endo presented the so-called "Gammaitoni Poster" at a joint scientific meeting of the American and Canadian Pain Societies. *See* Arnold Gammaitoni et al., *Presentations: Lidocaine patch 5% effectively treats neuropathic pain qualities in low back pain: results of a 6-week, prospective, open-label trial,* Vancouver, British Columbia: American Pain Society and Canadian Pain Society Second Joint Scientific Meeting (May 6-9, 2004). The presentation was led by Arnold Gammaitoni, a pharmacist employed by Endo.

232. The trial that led to the Gammaitoni Poster was of exceedingly poor and unreliable quality because it was designed as an open-label, non-randomized trial that was only two weeks in duration and had no control group. In every respect, it was inferior to Endo's already-completed Phase IV EN3220-011 study. Accordingly, its apparently contradictory conclusions were not simply unreliable, they were materially misleading.

233. In July 2005, approximately two years after Endo completed its Phase IV EN3220-011 study, the Endo-sponsored "Gimbel Study" was published. *See* Joseph Gimbel et al., *Lidocaine Patch Treatment in Patients with low Back Pain: Results of an Open-Label, Nonrandomized Pilot Study*, 12 AM. J. THERAPEUTICS 311 (2005).

234. Like the Gammaitoni Poster before it, the Gimbel Study was open label, non-randomized and lacked a control group. Thus, it, too, was demonstrably inferior to the already-completed Phase IV EN3220-011 study, and its conclusions were not simply unreliable, they were affirmatively misleading.

235. The lack of a control group for either the Gammaitoni Poster and Gimbel Study was most problematic, for without a control group, it was impossible for the investigators to discern whether a change in the study's endpoint was the result of the drug being investigated, the result of a "placebo effect", or the result of a natural progression of the patient's medical condition. The "placebo effect" is a particularly important issue in the field of pain management, where the placebo effect is known to be pronounced. Indeed, Endo's EN3220-011 study showed that an astonishing 58% of patients on the placebo reported either "moderate improvement", "a lot of improvement", or "complete improvement" over the course of the study. And Endo's EN3261-001 study showed that mean pain scores for patients on placebo decreased in excess of 30%. Thus, Endo's own clinically rigorous research shows that there was no way to determine whether the improvement experienced by patients in the Gammaitoni and Gimbel trials was the result of Lidoderm® or the placebo effect.

2. Endo Proactively Promoted the Gimbel Study Even Though It Knew Its Conclusions Were Materially Misleading

236. Endo knew that the results of the clinically rigorous EN3220-011 and EN3261-001 studies conclusively undermined any hope of expanding Lidoderm®'s FDA approval to include the treatment of low back pain. Endo also knew that the results of the EN3220-011 and EN3261-001 studies would, if made public, undercut the Company's effort to encourage physicians to prescribe Lidoderm® off-label for the treatment of low back pain. Thus, Endo suppressed the studies; but it did not stop there.

237. Endo issued a press release on May 7, 2005, proudly announcing the results of the Gimbel Study. The press release announced the results presented at the 2nd Joint Meeting of the American Pain Society ("APS") where the Gimbel data was presented. According to the press release quote from Dr. Gimbel, Lidoderm® was an "innovative" treatment for low back pain. Gimbel is quoted as saying that he looks "forward to evaluating Lidoderm® in placebo-controlled studies for these indications."

238. Of course, what Dr. Gimbel did not mention was that this placebo-controlled study had already been completed, but the results were not favorable in terms of proving the drug was more effective than the placebo. As it suppressed the EN3220-011 and EN3261-001 studies that showed Lidoderm® is no more effective than placebo for the treatment of low back pain, Endo proactively promoted the Gimbel study as evidence of the drug's efficacy for that purpose, and thus used the Gimbel Study to materially mislead physicians regarding the drug's efficacy and the state of the science.

239. In order to drive sales of Lidoderm®, Endo actively trained its sales force (including Relator Weathersby) to aggressively promote the Gimbel Study to physicians as evidence supporting the off-label use of Lidoderm® for the treatment of low back pain. Specifically, beginning in late 2006, Endo sales representatives (including Relator Weathersby and Partner B) were trained by Endo management to tout the benefits of Lidoderm® for the treatment of low back pain by citing the Gimbel Study as "scientific evidence" that Lidoderm® is effective for that use. Endo shipped cases of Gimbel Study reprints to each sales representative and instructed them to use them in detailing to physicians and to leave them with physicians, nurses, physicians' assistants and office managers when they left. Endo provided no training or

instruction on the EN3220-011 and EN3261-001 studies, and thus deliberately failed to disclose to physicians that the conclusions of the Gimbel Study were materially misleading.

240. Because Endo concealed clinically rigorous and relevant information regarding the efficacy of Lidoderm® for the treatment of low back pain even as it promoted manifestly inferior and unreliable contradictory studies, the manner in which it promoted Lidoderm® for low back pain was not truthful; rather it was false and materially misleading.

3. Endo Proactively Promoted the Nalamachu Study on Carpal Tunnel Syndrome Even Though It Knew Its Conclusions Were Materially Misleading.

241. Endo used the inferior-quality Nalamachu study to promote Lidoderm® for treatment of pain associated with carpal tunnel syndrome, despite its knowledge that better-quality evidence recommended against Lidoderm®'s effectiveness for this use. The Nalamachu study, Srinivas Nalamachu et al., *Lidocaine patch 5% for carpal tunnel syndrome: How it compares with injections: A pilot study*, 55 J. FAM. PRAC. 209 (2006), was an open-label, pilot study, which included a sample of only 40 patients. The study was funded by Endo; its lead author was a paid consultant for Endo; and the statistician was a hired contractor, presumably paid for by Endo. It concluded that Lidoderm® was as effective as corticosteroid injections for treating pain associated with carpal tunnel syndrome.

242. The Nalamachu study itself recognized the tentativeness of the study's findings, in light of its significant design limitations, stating that "[t]hese *preliminary* data from this *small open-label, pilot* investigation *suggest* the *possibility* that the lidocaine patch 5% *may be* a useful option for *some* patients" (emphases added). The study elaborates that the small patient population, short duration, and open-label and non-blinded design all limit the reliability of the

Nalamachu study's conclusion, and that "[f]urther controlled trials are needed to confirm the effects reported in this pilot study."

243. Of course, Endo had conducted just such a controlled clinical trial three years earlier, but decided to terminate that study early after an interim analysis showed that, if carried to completion, the study would have concluded that Lidoderm® was no more effective than placebo for treatment of carpal tunnel syndrome. *See supra* ¶¶ 204-10. That study, EN3272-301, was double-blinded and contained a patient population that was more than five times larger than the Nalamachu study, making EN3272-301 by far the more clinically rigorous of the two.

244. Nonetheless, Endo instead trained its sales representatives to misleadingly tout the Nalamachu study as definitive evidence of Lidoderm®'s effectiveness for treatment of pain from carpal tunnel syndrome. Specifically, in early 2007, Endo mailed its sales representatives a box containing hundreds of copies of the Nalamachu study. Inside the box was a letter from Endo's sales and marketing department instructing the sales force to hand out the clinical reprints during physician visits. Partner B did as he was instructed, distributing all copies of his copies of the Nalamachu study. Approximately one year later, Endo reversed course, directing its sales representatives to no longer hand out the Nalamachu study and instead ship to the Company any remaining copies.

245. By promoting Lidoderm® using the Nalamachu study, not only did Endo conceal the results of EN3272-301, both from physicians as well as from its own sales representatives, but it also omitted any reference to the significant design limitations of the Nalamachu study, suggesting to the contrary that it was a well-designed and rigorous study. As such, Endo deliberately misrepresented the available evidence regarding Lidoderm®'s effectiveness for treatment of pain from carpal tunnel syndrome to physicians, misleading them into believing that

Lidoderm® had been decisively shown to be effective for that use, when in actuality superior evidence demonstrated that it was not.

4. Endo Proactively Promoted the Binder Study Even Though It Knew Its Conclusions Were Materially Misleading.

246. Endo knew that the results of the clinically rigorous EN3220-009 study undermined any hope of expanding Lidoderm®'s FDA approval to include the treatment of neuropathic pain generally. Endo also knew that the results of the EN3220-009 study would, if made public, undercut the Company's effort to encourage physicians to prescribe Lidoderm® off-label for the treatment of neuropathic pain generally notwithstanding the lack of FDA approval. Thus, Endo suppressed the study; but it did not stop there.

247. As it suppressed the EN3220-009 study that showed Lidoderm® is no more effective than placebo for the treatment of neuropathic pain generally, Endo proactively promoted the Binder Study as evidence of the drug's efficacy for that purpose. For example, Partner B's former District Manager, Nick Masi, instructed his sales representatives to proactively promote the Binder Study as evidence that Lidoderm® should be prescribed for the treatment of neuropathic pain generally, and he even went so far as to highlight specific sections of the Study that he said pointed to that conclusion. Thus, Endo used the Binder Study to materially mislead physicians regarding the drug's efficacy and the state of the science.

5. Endo Improperly Uses the Binder Study to Promote Lidoderm® for the Treatment of Neuropathic Pain

248. Since approximately December 2009, Endo has encouraged its sales representatives, including Relator Weathersby and Partner B, to initiate discussions of the so-called "Binder Study" with the doctors they call upon. This study, published in June 2009, promotes the off-label proposition that "topical lidocaine therapy has recently been

recommended as first-line treatment for patients experiencing peripheral neuropathic pain symptoms" generally (i.e., whether or not the patient suffers from PHN). *See* Andreas Binder et al., *Topical 5% Lidocaine (Lignocaine) Medicated Plaster Treatment for Post-Herpetic Neuralgia*, 29 CLINICAL DRUG INVESTIGATIONS 393 (2009). Endo has created a clinical reprint of the Binder Study that it has distributed to its sales force, and which Endo has carefully highlighted to focus the reader's attention on off-label uses of Lidoderm® even though Endo knows that its own trials, which it suppressed, are contradictory. *See* discussion *supra* ¶¶ 192-213.

249. Despite the Binder Study's limited scope, Endo's sales representatives were trained to (and did) use it to promote Lidoderm for the treatment of other neuropathic pain conditions by (i) telling physicians that Lidoderm®'s efficacy with regard to PHN was indicative of its efficacy with regard to other neuropathic pain conditions, and (ii) focusing physicians' attention on statements in the Binder Study that Lidoderm®'s efficacy in treating other neuropathic pain conditions had been convincingly demonstrated in other studies. For instance, Endo trained its sales representatives to focus physicians' attention on the following statements in the Binder Study, which were highlighted as "evidence" that physicians should prescribe Lidoderm® for neuropathic pain generally:

- the statement that "[e]vidence-based recommendations for first line PHN treatments, *as well as for the treatment of neuropathic pain in general*," include Lidoderm® (emphasis added);
- the statement that the study "adds further weight to the growing body of clinical and research evidence" that Lidoderm® "is effective and well tolerated in patients

with neuropathic pain caused by zoster infection *and in other peripheral neuropathies with similar pain symptoms*" (emphasis added);

- the statement that the effects of Lidoderm® "are consistently supported by data from previous controlled clinical trials in patients with PHN *as well as in patients with other peripheral neuropathies with similar pain symptoms*" (emphasis added); and
- the statement that "topical lidocaine therapy has recently been recommended as first-line treatment for patients experiencing peripheral neuropathic pain symptoms" generally (i.e., whether or not the patient suffers from PHN).

250. Endo did this even though it knew that its own (suppressed) trials showed that Lidoderm® was not nearly so broadly effective, and thus its promotion of the Binder Study was false and materially misleading.

251. Relator Weathersby's supervisor, Desiree Smith, encouraged him and others to promote the Binder Study *sua sponte* as evidence that Lidoderm® should be prescribed for *all* forms of neuropathic pain, and to leave copies of the study with their sales targets whether or not they request it, and despite the fact that Endo has highlighted the document to emphasize off-label uses. Ms. Smith described this tactic as a way to "lead [doctors] down that path" to off-label use, and she erroneously stated that it is proper to do so because the Binder Study was conducted in Europe. She trained her sales team, including Relator Weathersby, in this tactic through role play exercises during training sessions and at nearly every sales meeting that Relator Weathersby attended. During these role play exercises, sales representatives were trained to rehearse sales pitches in which they would falsely introduce the Binder Study to physicians as a study that examined Lidoderm®'s ability to treat neuropathic pain generally.

252. In addition, Endo's website currently trumpets a recommendation of the "Fourth International Conference on the Mechanisms and Treatment of Neuropathic Pain" that Lidoderm® be used as first-line therapy generally, without limiting the recommendation to PHN. *See* http://www.lidoderm.com/recommends.aspx.

253. Endo also trains its sales representatives to coach physicians and medical office personnel on how to deal with Medicare and Medicaid payors who may refuse to reimburse Lidoderm® prescriptions written for off-label conditions. Specifically, sales representatives are taught to explain, and they do explain, how to complete reimbursement forms in a way that will not alert auditors that the prescription is for an off-label use.

D. ENDO DISTRIBUTES FREE SAMPLES OF LIDODERM® TO ILLEGALLY PROMOTE OFF-LABEL SALES AND USE OF THE DRUG BY FEDERAL PROGRAM BENEFICIARIES

254. Congress has recognized that the distribution of prescription drug samples can improperly influence health care professional conduct and negatively impact patient safety. Thus, the Prescription Drug Marketing Act ("PDMA") of 1987 governs the distribution of drug samples. The PDMA restricts the manner in which pharmaceutical companies may use samples of their prescription drug products. For example, companies such as Endo may not provide drug samples to health care professionals:

(i) if the health care professional intends to seek reimbursement from the Government for the sample;

(ii) if the health care professional intends to use the sample for his or her own personal use;

(iii) to reward the health care professional for his or her past prescribing habits, or as a financial inducement to encourage future prescriptions; or

(iv) if it is reasonably certain that the health care professional intends to prescribe the samples for an off-label use.

255. Nevertheless, Endo routinely, systematically, and intentionally has engaged in a nationwide scheme to use free samples to illegally promote off-label sales and use of Lidoderm®. At all times material hereto, Endo has done this with the expectation that such off-label uses will lead to the submission of false claims for reimbursement by Government Programs.

256. From its initial FDA approval in 1999 to this day, Lidoderm® has been approved by the FDA for only a single, narrow indication: "relief of pain associated with post-herpetic neuralgia." PHN is a rare condition, typically afflicting only about 200,000 individuals in the United States each year, and most of those persons are over the age of 60. Thus, the FDA-approved, on-label market for Lidoderm® has been relatively small, while there are numerous other alternative FDA-approved options to treat that condition.

257. From the outset, Endo understood that the financial success of Lidoderm® (and thus the financial success of Endo) would hinge on the Company's ability to expand the market for Lidoderm® beyond the few patients who would be treated for its sole on-label use. Thus, Endo developed a marketing scheme by which to encourage health care professionals to prescribe Lidoderm® not simply for the handful of PHN cases they might treat, but also for the many other cases in which patients complain of chronic and/or other forms of pain.

258. Endo has understood that it could not expand the market for Lidoderm® patients if it were to limit its promotional activities to the handful of doctors likely to treat patients for its limited on-label PHN use. Thus, since at least since 2006, Endo has instructed its sales force to distribute free samples of Lidoderm® to a wide array of health care professionals without regard

for whether those health care professionals are likely to treat patients who suffer from PHN, as well as to many health care professionals who do not treat PHN at all.

259. In fact, distributing free samples became a job requirement for all Endo sales representatives. Sales representatives were not given any guidance or restriction on the number of Lidoderm® samples that they were permitted to distribute, nor to whom. Instead, sales representatives were to distribute as much Lidoderm® as necessary to drive sales growth and meet sales quotas that had been set for them by the Company.

260. The strategy worked, as distributing free samples to doctors unlikely to treat PHN persuaded those doctors to prescribe Lidoderm® off-label for other forms of chronic pain. For example, when Relator Weathersby joined Endo in 2006, he was instructed to, and did, distribute free samples of Lidoderm® to rheumatologists who had been placed on his call list by Endo, even though rheumatologists rarely, if ever, treat PHN. Two of the rheumatologists to whom Relator Weathersby regularly provided such free samples were Dr. Linda Rockhold and Dr. Ann Myers, both of Jackson, Mississippi.

261. What Endo understood was that rheumatologists often treat patients who suffer from osteoarthritis—a chronic pain condition generally suffered by the elderly. Endo's expectation was that the rheumatologists would distribute the free samples off-label to their osteoarthritis patients, along with prescriptions for long-term use of the drug. It worked. The strategy was so successful that, when Relator Weathersby subsequently made sales calls on rheumatology practices, he observed elderly patients in waiting rooms with Lidoderm® patch cut-outs affixed to each of their knuckles—a location typically associated with the pain of osteoarthritis. Endo had succeeded in turning Lidoderm® into a sample-driven drug used by rheumatologists.

262. Similarly, Partner B has been directed to (and does) provide free Lidoderm® samples to physicians on his call list who did not treat PHN. On many occasions, these physicians have shared (and continue to share) with Partner B the critical fact that they do not treat patients who suffer from PHN, nor do they prescribe Lidoderm® for PHN. In fact, some of these physicians have admitted to Partner B that they do not even know what "PHN" stands for. The uses for which these physicians prescribe Lidoderm® are predominately off-label and, more specifically, include treating pain in the lower back, knees and neck. Notably, many, if not all, of these physicians make it clear to Partner B that they will stop prescribing Lidoderm® unless they continue to receive free samples of the drug. Some of the physicians referenced above include:

(i) Dr. Thomas Molloy (Cardiologist) Fairlawn, New Jersey; Dr. Molloy informed Partner B that he uses the Lidoderm® patch on some of his patients after open heart surgery. Dr. Molloy tells his patients to place the patch over the stitched area of the chest after such a procedure. When Partner B reminded Dr. Molloy that such use is off-label, Dr. Molloy responded that all of his prescriptions of Lidoderm® are for off label uses. Partner B promptly reported this to his District Manager, Nick Masi. Despite being fully aware of the off-label nature of Dr. Molloy's prescribing habits, Endo still directs Partner B to continue providing free Lidoderm® samples to Dr. Molloy in an effort to maintain his business. As a result of Endo's promotional activities, Dr. Molloy subsequently did write Lidoderm® prescriptions off-label.

(ii) Dr. Ahmad Kahf (Cardiologist) Haledon, New Jersey; Partner B received bi-weekly phone calls from Dr. Kahf's office asking him for free Lidoderm® patches. Upon speaking with Dr. Kahf about using Lidoderm® in the treatment of PHN, Dr. Kahf revealed that he actually does not treat PHN. However, Dr. Kahf also stated that Partner B needed to stop by his office on a more regular basis to provide free Lidoderm® samples, otherwise, Dr. Kahf would not prescribe the drug. While Dr. Kahf has since been removed from Endo's call lists, he nevertheless, for many years, received numerous free samples of Lidoderm® even after the Company was made aware of the fact that he does not treat PHN. Partner B estimates that approximately 20% of Dr. Kahf's patients are Medicare beneficiaries, while 15-20% are Medicaid recipients.

(iii) Dr. Elsayed Hussein (Internal Medicine); Brooklyn, New York; Dr. Hussein is one of Brooklyn's highest prescribing Lidoderm® physicians, who has stated he very rarely treats PHN. Partner B has visited Dr. Hussein on numerous occasions with his District Manager, Acho Ukegbu. During these joint visits, Endo continuously tried to persuade Dr. Hussein for more Lidoderm® prescriptions, knowing full well that the requested prescriptions are for off-label uses. Dr. Hussein subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 15% of Dr. Hussein's patients are Medicare beneficiaries, while 50% are Medicaid recipients.

(iv) Dr. Min Wong (Internal Medicine); Brooklyn, New York; Dr. Wong is another high volume Lidoderm® prescriber who has acknowledged to Endo that he rarely treats a PHN patient. While visiting Dr. Wong's office on December 12, 2011 with his manager, Acho Ukegbu, and on several other occasions, Endo pushed for more Lidoderm® prescriptions knowing that such prescriptions would be for off-label uses. As a result of Endo's promotional activities, Dr. Wong subsequently did write Lidoderm® prescriptions off-label. Partner B estimates that approximately 50% of Dr. Wong's patients are Medicare beneficiaries, while 40% are Medicaid recipients.

(v) Dr. Henry Chen (Internal Medicine) Brooklyn, New York; Dr. Chen has stated to Partner B that he will not prescribe Lidoderm® unless Endo provides free patches to his office. Dr. Chen is a high prescribing Lidoderm® physician who has shared with Partner B in the past that he rarely treats PHN. In fact, when Partner B first discussed PHN with Dr. Chen, the physician admitted he did not know what PHN stood for. Dr. Chen subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 66% of Dr. Chen's patients are Medicare beneficiaries, while 20% are Medicaid recipients.

(vi) Janlian Medical Group (Dr. Robin Chan (Internal Medicine); Dr. Fufu He (Internal Medicine; Family Practice) Brooklyn, New York; These physicians are very high prescribers of Lidoderm®. Both physicians have

stated to Partner B during ride-alongs with management, District Manager Acho Ukegbu, that they rarely prescribe Lidoderm® for PHN. DM Ukegbu has asked Partner B to visit this office on a regular basis to grow Lidoderm® prescriptions, fully aware that the prescriptions being requested are for off-label uses. Drs. Chan and He subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 25% of Dr. Chan's patients are Medicare beneficiaries, while 50% are Medicaid. Partner B further estimates that approximately 33% of Dr. He's patients are Medicare beneficiaries, while 38% are Medicaid recipients.

(vii) Dr. Zihe Shan (Internal Medicine) Brooklyn, New York; Another high prescribing Lidoderm® physician who has stated to Partner B that he does not treat PHN. Further, Dr. Shan has stated that if he does not continue to receive free samples of Lidoderm®, he will not prescribe it in the future. Dr. Shan continues to receive free Lidoderm® samples and also prescribes Lidoderm® for off-label uses as a direct result of Endo's promotional activities. Partner B estimates that approximately 30% of Dr. Shan's patients are Medicare beneficiaries, while 55% are Medicaid recipients.

(viii) Dr. Benjamin Wu (Family Practice) Brooklyn, New York; Dr. Wu has made it clear that he rarely uses Lidoderm® for PHN. Dr. Wu is another high prescribing Lidoderm® target who is being asked to increase his volume of Lidoderm® prescriptions with the Company's knowledge that the uses are off-label. Partner B has visited this office numerous times in

the past while with DM Ukegbu to deliver free samples and make a push for an increase in Dr. Wu's Lidoderm® business. As a result of Endo's off-label promotional activities, Dr. Wu subsequently did write Lidoderm® prescriptions off-label. Partner B estimates that approximately 61% of Dr. Wu's patients are Medicare beneficiaries, while 25% are Medicaid recipients.

(ix) Dr. Yanfeng Chen (Hematologist); Brooklyn, New York; Dr. Chen is a high prescribing Lidoderm® physician who has stated to Partner B on many occasions, including while accompanied by DM Ukegbu, that he rarely treats PHN. Even after sharing this information with Partner B and Ukegbu, Endo nevertheless persuaded Dr. Chen to increase his Lidoderm® prescription volume, knowing that the prescription being requested are for off label use. Partner B estimates that approximately 45% of Dr. Chen's patients are Medicare beneficiaries, while 41% are Medicaid recipients.

(x) Dr. Jonathon Chang (Family Practice); Brooklyn, New York; Dr. Chang is a high volume Lidoderm® prescriber who has stated in no uncertain terms to Partner B and his District Manager, Acho Ukegbu, that he does not treat PHN. However, Endo still pushes for more Lidoderm® business knowing that the additional prescriptions being requested are for the off label use of Lidoderm®. Dr. Chang subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 45% of Dr. Chang's patients are Medicare beneficiaries, while 35% are Medicaid recipients.

(xi) Dr. Pudchong Srisethnil (Endocrinologist) Paterson, New Jersey; Dr. Srisethnil is a physician who has stated that he does not use Lidoderm® for PHN and explained that he does not see patients who suffer from PHN. On many occasions Partner B has visited Dr. Srisethnil with his District Manager, Nick Masi, to push Dr. Srisethnil to write more scripts of Lidoderm® despite being fully aware that the prescriptions being requested are for off-label uses of the drug. As a result of Endo's promotional activities, Dr. Srisethnil subsequently did write Lidoderm® prescriptions off-label. Partner B estimates that approximately 25% of Dr. Srisethnil's patients are Medicare beneficiaries.

(xii) Dr. Robert Lintz (Gastroenterologist) Clifton, New Jersey; Dr. Lintz has consistently asked Partner B to leave Lidoderm® patches with his office so that he can use it on his own lower back, but that he does not otherwise treat patients with PHN. Dr. Lintz further stated to Partner B that by providing him with free samples, Endo will be setting a "reminder" for him prescribe Lidoderm® for his patients. Dr. Lintz subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 10% of Dr. Lintz's patients are Medicare beneficiaries.

(xiii) Dr. Shams Qureshi (Anesthesiologist) Clifton, New Jersey; Dr. Qureshi is a surgeon who, as a result of Endo's off-label promotional activities, prescribes Lidoderm® for his patients with lower back pain.

(xiv) Dr. Michael Loreti (Orthopedic Physician) Paramus, New Jersey; High volume Lidoderm® prescriber who has stated several times to Partner B that he does not treat PHN. On several occasions, while with his manager, Nick Masi, Partner B and Masi would ask Dr. Loreti to prescribe more Lidoderm® while being fully aware that the prescriptions being requested were for off-label usage. Dr. Loreti subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that approximately 20% of Dr. Loreti's patients are Medicare beneficiaries.

(xv) Dr. Alex Corazon (Infectious Disease) Paterson, New Jersey; Partner B's highest volume prescriber of Lidoderm® while working for Endo in the Paterson, New Jersey territory. Dr. Corazon stated to Partner B that if he were to use Lidoderm® for PHN, then he would have no use for it all insofar as ***all*** of his prescriptions are for off-label uses. Partner B visited Dr. Corazon with District Manager Nick Masi to push for more Lidoderm® scripts despite knowing that Dr. Loreti did not prescribe Lidoderm® for PHN. Dr. Corazon subsequently did write Lidoderm® prescriptions off-label as a result of Endo's promotional activities. Partner B estimates that at least 10% of Dr. Loreti's patients are Medicaid recipients.

263. Indeed, Endo has instructed its sales force to deliver free samples of Lidoderm® to specified health care professionals, but did not instruct them on the volume of free samples that they should deliver. Instead, Endo left that decision up to the sales representatives, who are

guided only by the knowledge that if they do not grow their sales volume to meet the Company's predetermined sales goals (which bears no relation to the prevalence of PHN in the population and cannot be met through on-label PHN use alone), they will be fired. Thus, Partner B has been instructed to "leverage your samples properly."

264. Endo plainly encouraged its sales representatives to use the free samples to increase Lidoderm® sales volume as much as possible, including through off-label use. Thus, notwithstanding the relatively small on-label patient population for Lidoderm® and its limited on-label dosing regimen, Endo issued **29,700** sample patches (99 cases X 300 patches/case) to Relator Weathersby between August 15, 2006 and April 9, 2010—an average of more than **1,100** samples per month. Endo knew that the potential on-label patient population within Relator Weathersby's sales district did not justify such volumes, but it issued the samples anyway, and it instructed him to use them as part of his promotional efforts to physicians who did not treat on-label conditions, because Endo understood that the only way to drive sales volume as it intended was to use the samples to drive off-label prescriptions.

265. Likewise, Partner B received a similar quantity of samples to distribute to physicians. At his POAs, he and the other sales representatives were regularly told by their District Manager they needed to "leverage" their samples properly in order to get prescriptions of Lidoderm®. They were to give free samples to get prescriptions. Indeed, their goal was a prescription for every free sample they provided.

266. In December 2009, Endo provided approximately 4800 sample Lidoderm® patches to Partner B and directed him to distribute them to physicians in order to induce them to prescribe Lidoderm®. Today, Endo provides Partner B with approximately 800 sample

Lidoderm® patches each month, again with the instruction that he distribute them to physicians in order to induce them to prescribe Lidoderm®.

267. Approximately one year ago, Endo instituted a more formal, Endo-controlled system to use free samples to promote off-label sales of Lidoderm®. Specifically, Endo implemented a computer-based program that identifies the health care professionals to whom the sales representatives should deliver free samples, the number of free samples that are to be delivered, and the frequency with which the samples should be delivered. Formalizing the former sampling scheme, this new computer program often instructs sales representatives to deliver large volumes of Lidoderm® to health care professionals, such as rheumatologists, who Endo knows are unlikely to have any occasion to treat PHN, but who are likely to prescribe Lidoderm® off-label for chronic conditions such as osteoarthritis, if they have enough free samples to encourage the off-label use.

E. ENDO USED "CREATIVE ACCOUNTING" TO CONCEAL LAVISH DINNERS DESIGNED TO INDUCE PHYSICIANS TO PRESCRIBE LIDODERM®

268. Endo has embarked on a brazen effort to induce physicians to prescribe Lidoderm®, and to reward high-volume prescribers, by treating them to lavish dinners at fancy restaurants (typically costing well in excess of $100 per person), while at the same time attempting to conceal what the Company was doing.

269. These events are not educational in nature, but are purely social events intended to induce or reward physician prescribing behavior. However, in order to create a "clean" paper trail, sales representatives have been instructed to use "creative accounting" to conceal the events' true nature. For example, Endo sales representatives typically (i) add names of people who did not attend the dinner to the roster of supposed attendees in order to reduce the perceived per capita cost of the dinners, (ii) request that the restaurants prepare falsified receipts that

misstate the true cost of the meals, and (iii) falsify reimbursement requests to suggest that the meals were in-office lunches when they were no such thing. This was a common practice then and is still a common practice today.

270. From the beginning of Partner B's employment with Endo in July of 2006, his District Manager, Nick Masi, made it clear that sales representatives were expected to be "creative" in their accounting practices when it came to submitting receipts for dinner programs sponsored by Endo. For example, one of the first instances in which Partner B witnessed this type of accounting occurred at a dinner that took place at the Turkish Kitchen in Manhattan, New York on December 5, 2006. Endo had paid Dr. Gordon M. Freedman from Astoria, New York to present a fifteen minute lecture on the topic of "New Opioid Treatment Options For The Continuum Of Care In Pain Management." The Endo employees in attendance that evening included Partner B, sales representatives Doug Wynn, Darren Helowicz and James Worsham as well as District Manager Mike Davis. And, despite having a number of physicians in the audience that evening, there were not enough attendees at the dinner program to justify the total cost of the bill, which was exorbitant. Doug Wynn telephoned Nick Masi from the restaurant to explain the situation. In response, Masi directed Wynn to adjust the names on the reimbursement forms in order to bring the cost of the dinner below $100 per person. Wynn did as he was instructed and added the names of physicians and Endo employees who were not in attendance.

271. In another of numerous such examples, Endo sponsored a speaker program on July 30, 2009, during which Dr. John Fritz gave a paid presentation on "Consideration for 1st line multimodal therapy for pain of PHN with Lidoderm." Held at the South City Grill in Jersey City, New Jersey, the program was attended by Partner B, Endo sales representatives Jeff

Palmer, Ken Sobek, Marvin Sepulveda, Hellane Freeman and Jeff Winchell, and District Manager Mike Davis. Similar to the previous example, the District Manager directed the sales representatives to add to the reimbursement forms the names of individuals who were not in attendance in order to justify the extravagant cost of the dinner and drinks provided to the physicians who were actually present at the program. Shortly after the dinner program, DM Masi circulated an email to the sales representatives in his district acknowledging the success of the program and highlighting the return on investment ("ROI") that Endo expected from sponsoring the dinner. Specifically, Masi referred to the "importance of follow-up with the attendees shortly after the Program to reinforce the product messaging while the Program is still 'fresh' in the minds of the customers."

272. Endo's accounting manipulation of its sponsored dinner programs in order to mask the Company's otherwise transparent effort to reward past prescribing practices or induce future prescribing of Lidoderm® was a company-wide scheme that is ongoing.

F. ENDO CREATES LIDODERM® CALL LISTS POPULATED BY PHYSICIANS WHO DO NOT TREAT POST-HERPETIC NEURALGIA

273. To further its Fraudulent Market Scheme, Endo provides its sales representatives with call lists that include the names of numerous physicians to whom they are required to promote Lidoderm®. These lists include specialists, such as orthopedists and rheumatologists, who typically did not treat patients suffering from PHN.

274. By directing its sales force to focus promotional efforts on physicians who specialize in the treatment of conditions *other than* PHN, Endo sent a clear message to its sales force that the focus of Lidoderm® marketing efforts should be on the treatment of as broad a range of pain conditions as possible, notwithstanding the fact that such treatment is beyond the scope of its only FDA-approved indication, PHN.

275. Recently, the Company has taken steps to eliminate orthopedists and rheumatologists from its Lidoderm® call lists. However, within the past two years, Endo created a new program that is designed to be an end-run around off-label marketing restrictions. The program is run through a third-party vendor called CCG Marketing Solutions ("CCG") in West Caldwell, New Jersey. Endo sales representatives are instructed to provide physicians with a pre-printed 3" x 5" card that states they can continue to receive free samples of Lidoderm® if they will complete a form located at www.PHNPrescriber.com stating that they treat patients who suffer from PHN. Although this paints a thin veneer of compliance, the form itself is pre-populated with a wide range of medical specialties, many of which would have no reason at all to treat patients with PHN, and to Relators' knowledge neither Endo nor CCG has ever audited the physician responses to determine whether they were either (i) actually submitted by the physicians themselves, or (ii) truthful. In fact, Endo sales representatives such as David Fier from Staten Island, New York regularly falsified these forms in order to "validate" the addition of physicians on their call lists.

G. ENDO PROMOTES LIDODERM® USING FALSE SUPERIORITY CLAIMS TO NEURONTIN® AND LYRICA®

276. One of the key goals of Endo's Fraudulent Marketing Scheme has been to increase sales of Lidoderm® by converting as many Neurontin® (gabapentin) and Lyrica® (pregabalin) prescriptions as possible to Lidoderm® prescriptions. To accomplish this, Endo promotes Lidoderm® as being more effective than Neurontin® and/or Lyrica® despite the fact that (i) there are no adequate head-to-head efficacy studies comparing the drugs, and (ii) their FDA-approved uses are not the same.

277. As indicated, the FDA will not approve a drug for a specific indication unless the drug's effectiveness has been demonstrated by "adequate and well-controlled clinical

investigations." 21 C.F.R. § 314. *See* discussion *supra*. While Lidoderm® is approved only for the treatment of PHN, Neurontin® has also been approved for the treatment of epilepsy, and Lyrica® (launched in September 2005) has also been approved for epilepsy, diabetic peripheral neuropathy ("DPN"), and fibromyalgia. Thus, the three drugs are not interchangeable.

278. Drug makers may not make comparative efficacy claims to physicians based on a simple comparison of product inserts (a product's approved labeling), nor may a drug maker's promotion to health care professionals compare two non-comparative trials (due to differences in trial designs, inclusion criteria and other factors).

279. In its promotion of Lidoderm® for these off-label indications, Endo also made unsubstantiated superiority claims that Lidoderm® was more effective than Neurontin® and Lyrica®. In fact, at least with regard to Neurontin®, Endo's own clinically rigorous study had shown those superiority claims to be false. In 2003, Endo had commissioned a multicenter, randomized, double-blind, placebo-controlled study, designated EN3220-009, which compared the efficacy of placebo, Lidoderm®, Neurontin®, and the combination of Lidoderm® and Neurontin®, for treatment of diverse peripheral neuropathic pain conditions. That study concluded there was no statistically significant difference between the Lidoderm® and Neurontin® treatment groups in any of the endpoints of average change in worst pain, least pain, pain now, or average daily pain. That is, Endo's superiority claims to the contrary, Lidoderm® was shown to be no more effective than Neurontin® in treating diverse neuropathic pain conditions.

280. Nevertheless, Endo has illegally instructed its sales force to promote Lidoderm® head-to-head against Neurontin® and Lyrica® as being more effective than each of them. This message is verbally conveyed by district sales managers to sales representatives, but it also is

conveyed in paper format. Endo has made its expectations clear by giving each sales representative a weekly sales report that compares each regional health care professional's volume of Lidoderm® prescriptions against his or her volume of Neurontin® and Lyrica® prescriptions. Endo's senior marketing management has regularly made clear to sales representatives that they are to use this information in order to prioritize their sales calls by focusing first on those doctors who write a high volume of Neurontin® and Lyrica® prescriptions, even if it meant going after non-PHN uses of these products.

H. ENDO DISGUISES ITS UNLAWFUL PROMOTION OF LIDODERM® FOR OFF-LABEL USES THROUGH ITS ENGAGEMENT OF PAID SPEAKERS

281. Endo routinely pays "key opinion leaders"—i.e., physicians who would influence their peers' medical practices including, but not limited to, prescribing behavior—to make presentations to groups of doctors in order to encourage them to prescribe Lidoderm® for more of their patients, including for off-label uses. The presentations are offered under the guise of providing "fair and balanced" information, but Endo selects its speakers based on the volume of Lidoderm® prescriptions they write (i.e., the more they write, the more likely they are to be hired) and the expectation (generally based on experience) that they will speak favorably about Lidoderm® and promote off-label uses of the drug.

282. Although Endo selects the presentation topics and provides a set of "approved" slides, it deliberately ignores the fact that its hired speakers routinely speak off-label using their own unapproved and off-label visual aids and data. More alarming, Endo sales personnel across the country routinely "planted" questions about off-label uses with trusted members of the audience in order to initiate such discussions.

283. These presentations generally are held at three- and four-star restaurants (e.g., Morton's Steak House in Hackensack, New Jersey, Napa Valley Grille in Paramus, New Jersey,

The River Palm Terrace in both Fairlawn and Edgewater, New Jersey, as well as many other upscale restaurants throughout the country). Although nominally excluded, in practice, guests routinely were permitted to bring their spouses. And although meal costs are supposed to be capped at $100 per person in order to comply with regulatory requirements, the speaker programs routinely exceed that amount and sales specialists across the country routinely fabricate names of additional "physician" attendees in order to reduce the per capita expenditures for record-keeping purposes. Speakers were paid from $1,500 to $2,500 for each presentation.

284. Dr. Grace Ford is a pain management specialist from Syosset, New York, whom Endo has paid to give presentations designed to encourage other doctors to prescribe Lidoderm®, including for off-label uses. Since Lidoderm® originally was approved by the FDA, Dr. Ford has given numerous presentations every year, and has been paid approximately $1,500 to $2,500 per presentation.

285. Endo sales specialists routinely asked questions at these and other presentations in order to initiate discussions that would promote off-label uses of Lidoderm®. For example, during a presentation given by Dr. John Fritz at South City Grill in Jersey City, New Jersey on May 7, 2009, Endo sales representative Ken Sobek asked Dr. Fritz whether he used the Lidoderm® patch to treat low back pain. In response to the question posed, Dr. Fritz told the assembled audience of some sixteen doctors and staff that there are many uses for Lidoderm® beyond its labeled indication, including off-label for the treatment of low back pain. As a high prescriber of Lidoderm®, Dr. Fritz was rewarded with numerous opportunities to make similar paid presentations during which he invariably addressed off-label uses of the product.

286. In another example, Dr. Kenneth Park gave a dinner presentation at The River Palm Terrace restaurant in Edgewater, New Jersey on November 12, 2009. During the

presentation, which addressed integrating new clinical data into PHN pain management, sales representative Sobek again proactively asked Dr. Park if he regularly uses Lidoderm® to treat patients suffering from low back pain. Dr. Park responded by discussing the use of Lidoderm® in treating this off-label condition and opened the off-label discussion to other physicians in attendance.

287. As part of their measurement of the success of these speaker programs, Endo management regularly tracked the return on its investment ("ROI") associated with its speaker programs by measuring increases in its market share compared to other pain medication. For example, Partner B's former district manager, Nick Masi, regularly discussed ROI for speaker programs, and directed sales representatives (including Partner B) to follow-up with attendees to make certain the physicians understood the off-label Lidoderm® message.

I. ENDO USES QUOTA AND BONUS PROGRAMS TO DRIVE OFF-LABEL PROMOTION OF LIDODERM®

288. Endo's Lidoderm® sales strategy includes quota and bonus programs that motivate sales representatives to sell Lidoderm® to health care professionals who do not treat PHN. Endo knows that these programs create a working environment conducive to promoting Lidoderm® for as many uses as possible, and for as wide a patient base as possible. The quota and bonus programs were instituted and have been applied to sales representatives, District Managers, Regional Managers, and Vice Presidents.

289. Endo's quota system requires Lidoderm® sales representatives to detail all physicians on their call lists (regardless of specialty), and it awards bonuses based on sales of Lidoderm®. At all times material hereto, and at least since 2006, the only way the sales representatives could meet the quotas that were set for them was by promoting Lidoderm® off-label.

290. One of the key quotas for all Endo sales representatives is that they are "weighted against" Neurontin® and Lyrica®, which have a number of FDA-approved indications beyond Lidoderm®'s single FDA-approved indication for PHN. All sales representatives have been given call lists of physicians who are prescribing Neurontin® and/or Lyrica®. Despite the fact that Neurontin® and Lyrica® have different FDA-approved indications than Lidoderm®, Endo's sales goals are set based on capturing sales from doctors who prescribe Neurontin® and/or Lyrica®, and these goals are specifically aimed at winning Lidoderm® sales from these doctors.

291. At all times material hereto, and since at least 2006, Endo senior sales management has, at all national and local POA sales meetings, regularly insisted that sales representatives go after the broader Lyrica® market, in particular, even though Lidoderm® has not been approved for the additional epilepsy, DPN or fibromyalgia uses that Lyrica® has.

292. As part of the Fraudulent Marketing Scheme, Endo expects and instructs its sales representatives to highlight Lidoderm®'s allegedly superior side effect and safety profile in comparison to Lyrica®, despite the fact that there are no head-to-head studies to support such a comparison.

293. Moreover, sales representatives are expected to promote Lyrica® and Lidoderm® as combination therapy (i.e., using both drugs together) to treat the same kinds of pain. Indeed, they are told to tell health care professionals that Lyrica® treats pain "inside out" while Lidoderm® treats pain "outside in." Endo sales representatives follow this instruction. Not only is this promotion deliberately misleading because Lidoderm® has fewer indications than Lyrica® (and thus may not be used to treat the same conditions as Lyrica®), it also is deliberately misleading in that the promotion illegally conveys the impression that Lidoderm® has been approved for use in combination with Lyrica® when that is not the case.

294. Finally, many of the prescribers who Endo includes in its quota and bonus programs are doctors who would not normally treat patients with PHN, including numerous rheumatologists, internists, and family practitioners. While these doctors may, on rare occasions, have used Lidoderm® on-label for the treatment of PHN, the vast majority of these physicians would only use Lidoderm® off-label.

295. Endo sales representatives have followed, and continue to follow the illegal marketing tactics outlined above, resulting in improper and illegal reimbursements by Federal Programs.

J. ENDO USED CONSENSUS CLINICAL PRACTICE GUIDELINES IT FUNDED IN ORDER TO TOUT OFF-LABEL USE OF LIDODERM®

296. A key part of Endo's Fraudulent Marketing Scheme has been the development and use of clinical practice guidelines ("Guidelines") to promote the off-label use of Lidoderm®. These Guidelines are summaries of "expert" opinion that are often used to identify standards of care. Guidelines are an important source of drug information for physicians, particularly when there is no prescribing information available on the product insert. Guidelines are typically formulated by panels of experts under the auspices of medical professional societies, non-profit organizations, or quasi-governmental organizations.

297. Two such Guidelines were developed to provide treatment guidelines for general neuropathic pain with support of Endo: (i) Dworkin, *et al.*, "Advances in Neuropathic Pain: Diagnosis, Mechanisms, and Treatment Recommendations," ARCHIVES OF NEUROLOGY, 60:1524-1534 (2003) (the "Archives Guidelines"); and (ii) Dworkin, *et al.*, Pharmacologic Management of Neuropathic Pain: Evidence-Based Recommendations," PAIN 132:237-251 (2007) (the "IASP Guidelines") (collectively, the "Neuropathic Pain Guidelines"). The Neuropathic Pain Guidelines tout the off-label use of Lidoderm® in the treatment of neuropathic

pain. Both were funded at least in part by Endo and have been regularly used to promote off-label use of Lidoderm® in the treatment of general neuropathic pain.

298. Both Guidelines here have substantial overlap in the study panel experts. In addition, many of the Guideline panel experts have economic ties to Endo via research grants or speaker fees. These financial relationships with Endo "may create conflicts of interest and a risk of undue influence on judgment both for entities that sponsor the development of clinical practice guidelines and for the individuals who participate in their development." *See* BERNARD LO & MARILYN J. FIELD, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE, INSTITUTE OF MEDICINE 183 (2009).

299. Relationships with Endo (and other drug makers) and conflicts of interest in the development of Guidelines exist at both the individual level (i.e., panel participants may have industry ties) and the institutional level (i.e., the sponsoring group may rely on industry funding for guidelines). These relationships raise the obvious concern of conflicts of interest and undue influence at each step in the development process of the Guidelines. Consensus groups that require industry funding for the development of practice guidelines propose topics that will attract industry funding (e.g., a guideline on how to use a product but not whether it should be used).

300. Exactly how much Endo contributed to each author or to the Neuropathic Pain Guidelines is unclear. Nor is it clear the precise role Endo played in the development of the Neuropathic Pain Guidelines. The lack of transparency of conflict of interest policies in the Guidelines "limits the ability of guideline readers to consider financial relationships and conflicts of interest as part of their assessment of the credibility of a set of guidelines." *See* LO & FIELD, at 205.

301. Here, the Endo-supported Neuropathic Pain Guidelines were designed to create overwhelming use of Lidoderm® by producing a set of step-by-step treatment decision trees approved as first- and second-line treatments for general neuropathic pain. For example, both of the Guidelines recommend the off-label use of Lidoderm® as first-line in the treatment of neuropathic pain.

302. Endo regularly used the Neuropathic Pain Guidelines in sales details to encourage health care professionals to use Lidoderm® off-label. In fact, the Archives Guidelines are still cited today on Endo's website in support of off-label use of Lidoderm® to treat neuropathic pain. *See* http://www.lidoderm.com/recommends.aspx (last updated December 21, 2011).

303. In addition, Relator Weathersby, Partner B and other Endo sales representatives were required to use the IASP Guidelines in their sales details, even though the guidelines tout Lidoderm® as first-line in the off-label treatment of neuropathic pain.

K. ENDO USES "DOCTOR-FOR-A-DAY" PROGRAMS TO INDUCE PHYSICIANS TO PRESCRIBE LIDODERM®

304. Since at least 2006, Endo trained and directed its sales representatives to use "Doctor-For-A-Day" programs as one means of providing an illegal kickback to physicians for prescribing Lidoderm® beyond its FDA-approved label. Under this program (also called "Specialist-For-A-Day"), Endo paid physicians to ride with Endo sales representatives on their sales calls to other physicians, and to assist them in promoting additional off-label uses of Lidoderm®.

305. This program was a very successful, thinly-veiled effort by Endo to (i) disguise an illegal effort to financially reward high-prescribing physicians, and (ii) pay those high-prescribing physicians in furtherance of its off-label promotional efforts.

306. Endo acknowledged the illegality of these and related promotional programs when it terminated support for them effective September 1, 2010. The decision to terminate the programs was communicated to Relator Weathersby (and the other sales representatives in his District) in an email from District Manager Desiree Smith (copied to Regional Manager Ron Jackson) on August 5, 2010. That email stated:

> In an effort to make sure Endo remains compliant and adapts to changes in Health Care laws/regulations, a change has been made to the Speaker program. Effective September 1st, we can no longer conduct Specialist for a Day, 1:1, or Roundtable programs. The types of programs that will be available after September 1st are Breakfast, Lunch, Dinner, Teleconference, and WebEx. These programs have to be held in a private room, with multiple attendees, and at an appropriate venue.

307. This email confirms (i) that the programs took place, (ii) that non-compliance extended to a variety of speaker programs, and (iii) that Endo waited until September 1, 2010 to bring itself into compliance.

L. ENDO USES OFF-LABEL MASTER VISUAL AIDS TO PROMOTE LIDODERM®

308. Endo supplies its sales representatives with Master Visual Aids ("MVAs") for Lidoderm® that they are instructed to leave at physician offices. On the back of one such MVA is a picture of a prescription pad in which Endo spells out for the physician how to write a prescription in a way that will not trigger scrutiny from payors that would not otherwise reimburse for the off-label use of Lidoderm®. The directive reads: "Apply as directed. Up to 3 patches a day for 12 hours. Apply to area of greatest pain over intact skin only." Endo has determined that a Lidoderm® prescription written in this way will be reimbursed by Medicare or Medicaid, even though the prescription may be for an off-label use. Endo thus provides a tutorial to maximize the opportunities for doctors to write prescriptions for off-label conditions while manipulating limitations intended to ensure only on-label reimbursement by Federal Programs.

309. An email from Desiree Smith, Relator Weathersby's District Manager, confirms that Endo directs its sales representatives to illegally promote the off-label uses of Lidoderm®. In the June 25, 2010 email, Smith presented sales representatives in her district with "key strategic imperatives" for selling Endo's pain management products. For Lidoderm®, Smith instructed the sales representatives to "[u]tilize your visuals and sell on efficacy in treating PHN *and allodynia* that is sometimes associated with PHN." (Emphasis added).

310. Lidoderm® is not approved to treat allodynia, and for good reason. Allodynia can be associated with and/or caused by countless other painful conditions such as neuropathies, complex regional pain syndromes, fibromyalgia, spinal cord injury and even migraine headaches. Allodynia simply means "other pain" or "pain produced by a non-noxious stimulus." It is due to a stimulus that does not normally lead to the sensation of pain, and often occurs after injury to a site. While some PHN sufferers do experience the symptoms of allodynia, they are not experienced by every PHN patient. Ms. Smith's instruction to promote Lidoderm® for the treatment of allodynia is improper because such treatment is off-label, but it is consistent with Ms. Smith's frequent instruction to the sales force to "lead the doctor down the path of neuropathic pain" when promoting Lidoderm®.

311. Similarly, Nick Masi (Partner B's former District Manager) often provided his sales team the identical instruction: "lead the doctor down the path of neuropathic pain." Masi strongly suggested that it was Endo's policy to train the sales force in that fashion. For example, during ride-alongs with sales representatives, Masi would sit in the car with the sales representatives before each sales call and give them the open-ended question he wanted the sales representatives to ask each physician. Specifically, Masi's role play would involve asking the physician, "Doctor, when you treat a patient that complains of deep aching pain (point to your

lower back), or a type of pain in which the patient can point to and has symptoms of burning, stabbing or shooting pain, how do you determine what medication to use for this patient and have you ever considered using Lidoderm for this patient type?" Masi would then role-play with the sales representative to make sure they asked the proper question that would lead the physicians down a particular path to off-label use.

312. Partner B expressed his concern with Masi that he did not feel comfortable leading the physician down that path because it opens up an off-label discussion for Lidoderm®. Masi assured Partner B that it would not open up an off-label dialogue, but instead would "plant the seed" and "paint the picture" that Lidoderm® can be used off-label in the treatment of back pain as well as other general neuropathic conditions.

XI. DEFENDANTS' ILLEGAL MARKETING AND KICKBACK ACTIVITIES CAUSED THE SUBMISSION OF FALSE CLAIMS TO FEDERAL PROGRAMS AND QUI TAM STATES.

313. Defendants' Fraudulent Kickback Scheme was successful in securing favorable formulary treatment for Endo's drugs in exchange for the distribution of free Endo drug products to Defendant Hailey's mother. The result has been the improper and illegal submission of claims for reimbursement by Federal Programs, and those claims were reimbursed.

314. Defendant Endo's Fraudulent Marketing Scheme also served its intended purpose, as it has induced doctors to write off-label prescriptions for Lidoderm®, and as it has induced the submission of claims for reimbursement of those prescriptions by Federal Programs. And, the Federal Programs did, in fact, reimburse those claims for off-label uses.

315. At least in part as a result of Endo's illegal sales and marketing practices, Lidoderm® has been heavily used for the treatment of Medicaid, Medicare Part D, and other Federal Program participants.

316. Between the third quarter of 1999 and the third quarter of 2009 (the last period for which such data is publicly available), Medicaid reimbursements for Lidoderm® totaled almost $850 million, covering more than one million prescriptions. It is estimated that Medicare Part D reimbursement of Lidoderm® is significant as well.

317. Likewise, as a result of Defendants' illegal kickback activities, Endo's drugs have been heavily used for treatment of Medicaid, Medicare Part D and other Federal Health Care Program participants.

XII. ENDO'S RETALIATION AGAINST RELATOR WEATHERSBY

318. On two separate occasions, Endo illegally reprimanded Relator Weathersby in response to his having come forward to report the Company's illegal sampling activities and kickback scheme for internal investigation. Specifically:

(i) Relator Weathersby internally reported, and complained about the impropriety of directives from his District Manager, Desiree Smith, to deliver large quantities of free Lidoderm® samples to Dr. James Polk, the physician treating Defendant Hailey's mother, Shirley Bufford, in exchange for favorable treatment of Endo's products on the formularies controlled by Hailey; and

(ii) Relator Weathersby internally reported, and complained about the impropriety of, directives from an Endo Senior Corporate Account Executive, Stephen Musial, that Relator Weathersby take additional samples to Dr. Polk, also for ultimate free distribution to Defendant Hailey's mother.

319. Endo's written compliance rules encourage employees to express any concerns they may have about certain Endo practices without fear of retaliation. In reliance, Relator Weathersby reported his concerns about the illegal sampling and kickback scheme to Endo's Corporate Compliance & Business Practices department, as well as to the Company's Human Resources department. Relator Weathersby explained his concerns, in detail, to Endo's Vice President of Corporate Compliance & Business Practices (Colleen Craven) and to its Director of Corporate Compliance & Business Practices (Joshua Drew), who then reported this information to the department of Business Partner Human Resources (Traci Shyer).

320. Specifically, in January, February and March of 2010, Relator Weathersby relied upon Endo's reporting policy and provided the aforementioned Endo personnel with specific information regarding sampling directives and activities that he believed, in good faith, were in violation of Endo's policies and Federal law insofar as the Company: (i) provided an inducement to an Endo customer with the intent to influence that person to recommend or purchase a health care product that may be reimbursed by a federal health care program; (ii) provided something to a customer in exchange for an implicit or explicit agreement or understanding to use, purchase, order, recommend, prescribe or dispense any Endo product; and (iii) improperly used prescription drug samples other than in response to a licensed practitioner's written request.

321. The substance and specificity of Relator Weathersby's complaints to his supervisors—particularly his complaint that the Company was unlawfully providing inducements to the mother of a health plan executive and customer (implicitly for the purpose of securing favored formulary status for Endo's drugs, and thereby causing additional prescriptions to be written for Federal Program beneficiaries)—were such that Endo should or could have

anticipated that Relator Weathersby was contemplating filing a *qui tam* action against it, or otherwise reporting Endo to the Federal Government or *Qui Tam* States for fraud.

322. In response to his complaints, beginning in March 2010, Relator Weathersby's supervisors retaliated against him by forcing him to work in a hostile work environment. For example, it was only then that, after a ride-along with Desiree Smith, Relator Weathersby received his first negative field evaluation in his career at Endo. When he sought an explanation for his poor review performance review, Smith refused to put her concerns in writing, preferring to handle the matter over the telephone. In response, Relator Weathersby began to (legally) record his telephone conversations with Endo supervisors and managers.

323. It was during a conference call on April 16, 2010 with Human Resources Business Partner Traci Shyer and Regional Manager Ron Jackson, that Ms. Shyer accused Relator Weathersby of being "out to get" Desiree Smith. Ms. Shyer said there was no evidence that Desiree ever threatened Relator Weathersby and that it was his word against Ms. Smith's.

324. Soon thereafter, Relator Weathersby received a formal warning letter, dated April 16, 2010 and signed by Ms. Shyer, citing what Shyer deemed to be Relator Weathersby's "exceedingly poor judgment" in recording telephone conversations, and warning that any further violation of Endo's Code of Conduct "will result in a recommendation for termination."

325. It is no coincidence that Relator Weathersby received his first poor performance review and negative treatment by his managers, including Ms. Smith, just after he internally reported his managers, including Ms. Smith, for violating Company policy and Federal law relating to illegal sampling and kickbacks.

326. The afternoon after the April 16, 2010 conference call among Relator Weathersby, Ms. Shyer and Mr. Jackson, Relator Weathersby began to experience chest pains,

shortness of breath, anxiety, and increased heart rate. He was admitted into the emergency room at the Mississippi Baptist Medical Center in Jackson, Mississippi, and was placed under the care of Dr. Eric Zoog. Dr. Zoog concluded that the issues were most likely directly related to, and caused by, what Relator Weathersby was experiencing in the workplace. Dr. Zoog recommended that Relator Weathersby stay home from work for one week and follow up with his personal doctor. Relator Weathersby saw his personal doctor the next week and he was prescribed treatment on a drug called Ramipril for high blood pressure.

327. Unfortunately, the hostile work environment continued unabated, culminating on May 20, 2010, when he participated in a conference call to review the outcome of the Company's internal compliance investigation into the illegal sampling activities that he had reported. The call was led by Traci Shyer with Ron Jackson and Desiree Smith also participating; inexplicably, the Company's Compliance Department did not participate. Ms. Shyer stated that the investigation was completed and that Relator Weathersby was being reprimanded and given a written warning because he had been involved in an illegal kickback scheme. She would not say whether any other person involved in the scheme had been disciplined in any way. Relator Weathersby was emailed a copy of the written warning, and he was asked to sign it and then return it to Shyer. Relator Weathersby was stunned to learn that he was being reprimanded in retaliation for his decision to follow Company policy and report improper activity that had been directed by his supervisors.

328. On May 25, 2010, while working in Philadelphia, Mississippi, Relator Weathersby began to suffer heart palpitations, anxiety, and shortness of breath. He immediately went to Airpark Medical Clinic (in Philadelphia, Mississippi) where he was examined by Dr. Robert K. Partrige. Relator Weathersby was treated for the above conditions along with high

blood pressure. Relator Weathersby was treated with Bystolic® and Xanax®, directed to stay away from work, and placed on short-term disability leave.

329. Plainly, Endo, through Shyer, Jackson, Smith and others, sought to and did repeatedly intimidate, punish and retaliate against Relator Weathersby for his lawful and proper decision to follow Company policy and report what he (accurately) considered to be illegal directions and activities by his supervisors. As such, the Company improperly made Relator Weathersby to suffer in a hostile work environment. As a direct and proximate result of this unlawful and repeated harassment and retaliation, Relator Weathersby has suffered emotional pain and mental anguish, as well as physical injuries

COUNT I

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A)[1])

330. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

331. Defendants knowingly presented or caused to be presented to the Government false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A).

332. As a result of Defendants' actions as set forth above in this Third Amended Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT II

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B)[2])

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[1] To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

[2] To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

333. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

334. Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of a false or fraudulent claim, thereby causing false or fraudulent claims for payment to actually be paid or approved, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

335. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Lidoderm® prescribed to patients enrolled in Federal Programs.

336. As a result of Defendants' actions as set forth above in this Third Amended Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT III

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C)[3])

337. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

338. As detailed above, Defendants knowingly conspired with health care professionals and providers, and each other, to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). Defendants and these health care professionals and providers committed overt acts in furtherance of the conspiracy as described above.

[3] To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

339. As a result of Defendants' actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(7))

340. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

341. As detailed above, Endo knowingly avoided or decreased its obligations to pay or transmit money to the Government. Specifically, Endo: (i) made, used, or caused to be made or used, a record or statement to conceal, avoid, or decrease an obligation to the United States; (ii) the records or statements were in fact false; and (iii) Endo knew that the records or statements were false.

342. As a result of Endo's actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT V
(Violation of False Claims Act, 31 U.S.C. § 3730(h))
(As Against Endo)

343. Relators incorporate herein by reference all allegations set forth in this Third Amended Complaint, as though fully set forth herein.

344. Between or about in January 2010 through July 2010, Relator Weathersby was threatened, harassed and discriminated against in the terms and conditions of his employment by Endo, all in retaliation for lawful acts taken by Relator Weathersby to report violations of the False Claims Act and in retaliation for other lawful acts taken by Relator Weathersby in furtherance of an action under the False Claims Act.

345. Endo's official reprimand of Relator Weathersby and his subsequent medical treatment are a direct result of Endo's retaliatory acts, which have proximately caused Relator

Weathersby to suffer and to continue to suffer substantial damage, in an amount to be proven at trial.

COUNT VI
(Violation of California False Claims Act)

346. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

347. This is a civil action brought by Relators, on behalf of the State of California, against Defendants under the California False Claims Act, Cal. Gov't Code § 12652(c).

348. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

349. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

350. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California, or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

351. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

352. As a result of Defendants' actions as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VII
(Violation of Colorado Medicaid False Claims Act)

353. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

354. This is a civil action brought by Relators, on behalf of the State of Colorado, against Defendants under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).

355. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

356. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

357. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

358. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

359. As a result of Defendants' actions as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VIII
(Violation of Connecticut False Claims Act)

360. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

361. This is a civil action brought by Relators, on behalf of the State of Connecticut, against Defendants under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301d.

362. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent

claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

363. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).

364. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).

365. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

366. As a result of Defendants' actions as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT IX
(Violation of Delaware False Claims and Reporting Act)

367. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

368. This is a civil action brought by Relators, on behalf of the State of Delaware, against Defendants under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1203(b).

369. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

370. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

371. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 120l(a)(7).

372. The State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of healthcare programs funded by the State of Delaware.

373. As a result of Defendants' actions, the State of Delaware and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT X
(Violation of District of Columbia False Claims Act)

374. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

375. This is a civil action brought by Relators, on behalf of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code § 2-308.15(b).

376. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(1).

377. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

378. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).

379. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

380. As a result of Defendants' actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XI
(Violation of Florida False Claims Act)

381. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

382. This is a civil action brought by Relators, on behalf of the State of Florida, against Defendants under the Florida False Claims Act, Fla. Stat. § 68.083(2).

383. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

384. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

385. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

386. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

387. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Georgia False Medicaid Claims Act)

388. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

389. This is a civil action brought by Relators, on behalf of the State of Georgia, against Defendants pursuant to the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

390. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

391. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

392. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

393. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

394. As a result of Defendants' actions, as set forth above, the State of Georgia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIII
(Violation of Hawaii False Claims Act)

395. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

396. This is a civil action brought by Relators, on behalf of the State of Hawaii, against Defendants under the Hawaii False Claim Act, Haw. Rev. Stat. § 661-25.

397. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

398. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

399. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

400. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

401. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIV

(Violation of Illinois False Claims Whistleblower Reward and Protection Act)

402. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

403. This is a civil action brought by Relators, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/4(b).

404. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois, or a member of the Illinois National Guard, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

405. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

406. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

407. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

408. As a result of Defendants' actions, as set forth above, the State of Illinois and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Indiana False Claims and Whistleblower Protection Act)

409. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

410. This is a civil action brought by Relators, on behalf of the State of Indiana, against Defendants under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-4(a).

411. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(1).

412. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

413. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

414. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

415. As a result of Defendants' actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Louisiana Medical Assistance Programs Integrity Law)

416. Relators incorporate herein by reference the preceding paragraphs of the Third Amended Complaint as though fully set forth herein.

417. This is a civil action brought by Relators, on behalf of the State of Louisiana's medical assistance programs, against Defendants under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.

418. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

419. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

420. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).

421. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

422. As a result of Defendants' actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Maryland False Health Claims Act)

423. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

424. This is a civil action brought by Relators, on behalf of the State of Maryland, against Defendants under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.

425. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

426. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

427. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

428. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

429. As a result of Defendants' actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Massachusetts False Claims Act)

430. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

431. This is a civil action brought by Relators, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).

432. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

433. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

434. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

435. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

436. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of Michigan Medicaid False Claims Act)

437. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

438. This is a civil action brought by Relators, on behalf of the State of Michigan, against Defendants under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.610a(1).

439. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or

false representations of a material fact in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

440. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

441. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).

442. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented or caused to be made or presented, and may still be making, presenting or causing to be made or presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

443. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

444. As a result of Defendants' actions, as set forth above, the State of Michigan and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of Minnesota False Claims Act)

445. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

446. This is a civil action brought by Relators, on behalf of the State of Minnesota, against Defendants under the State of Minnesota False Claims Act, Minn. Stat. § 15C.05(a).

447. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

448. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

449. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

450. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

451. As a result of Defendants' actions, as set forth above, the State of Minnesota and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
(Violation of Montana False Claims Act)

452. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

453. This is a civil action brought by Relators, on behalf of the State of Montana, against Defendants under the Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).

454. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

455. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

456. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

457. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

458. As a result of Defendants' actions, as set forth above, the State of Montana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII
(Violation of Nevada False Claims Act)

459. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

460. This is a civil action brought by Relators, on behalf of the State of Nevada, against Defendants under the Nevada False Claims Act, Nev. Rev. Stat. § 357.080(1).

461. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

462. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

463. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

464. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

465. As a result of Defendants' actions, as set forth above, the State of Nevada and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of New Jersey False Claims Act)

466. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

467. This is a civil action brought by Relators, on behalf of the State of New Jersey, against Defendants pursuant to the New Jersey Fraud False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

468. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

469. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

470. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

471. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

472. As a result of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of New Mexico Medicaid False Claims Act)

473. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

474. This is a civil action brought by Relators, on behalf of the State of New Mexico, against Defendants under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7(B).

475. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

476. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

477. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

478. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

479. As a result of Defendants' actions, as set forth above, the State of New Mexico and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of New York False Claims Act)

480. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

481. This is a civil action brought by Relators, on behalf of the State of New York, against Defendants under the New York False Claims Act, N.Y. State Fin. Law § 190(2).

482. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer, employee or agent of the State of New York, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

483. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved by the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(b).

484. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

485. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

486. As a result of Defendants' actions, set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of North Carolina False Claims Act)

487. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

488. This is a civil action brought by Relators, on behalf of the State of North Carolina, against Defendants under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).

489. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

490. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

491. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

492. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

493. As a result of Defendants' actions, as set forth above, the State of North Carolina and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of Oklahoma Medicaid False Claims Act)

494. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

495. This is a civil action brought by Relators, on behalf of the State of Oklahoma, against Defendants pursuant to the Oklahoma Medicaid Fraud False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).

496. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

497. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

498. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

499. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

500. As a result of Defendants' actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Rhode Island False Claims Act)

501. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

502. This is a civil action brought by Relators, on behalf of the State of Rhode Island, against Defendants pursuant to the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).

503. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Rhode Island, or a member of Rhode Island's National Guard, false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

504. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

505. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

506. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

507. As a result of Defendants' actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Tennessee Medicaid False Claims Act)

508. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

509. This is a civil action brought by Relators, on behalf of the State of Tennessee, against Defendants under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b).

510. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

511. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid

for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

512. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

513. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

514. As a result of Defendants' actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Texas Medicaid Fraud Prevention Act)

515. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

516. This is a civil action brought by Relators, on behalf of the State of Texas, against Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).

517. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or

misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

518. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

519. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

520. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making, claims under the Medicaid program for a service or product that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

521. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

522. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXI
(Violation of Virginia Fraud Against Taxpayers Act)

523. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

524. This is a civil action brought by Relators, on behalf of the Commonwealth of Virginia, against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).

525. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

526. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

527. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

528. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

529. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXII
(Violation of Wisconsin False Claims for Medical Assistance Law)

530. Relators incorporate herein by reference the preceding paragraphs of this Third Amended Complaint as though fully set forth herein.

531. This is a civil action brought by Relators, on behalf of the State of Wisconsin, against Defendant under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(5)(a).

Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the State of Wisconsin, or its political subdivisions, false or fraudulent claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(a).

Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, false records or statements to obtain approval or payment of false claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(b).

The State of Wisconsin, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

532. As a result of Defendants' actions, as set forth above, the State of Wisconsin and/or its political subdivisions have been, and may continue to be, severely damaged.

WHEREFORE, Relators pray for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Colo. Rev. Stat. § 25.5-4-304 *et seq.*; Conn. Gen. Stat. § 17b-301a *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Ga. Code Ann. § 49-4-168 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Ind. Code § 5-11-5.5 *et seq.*; La. Rev. Stat. Ann. § 46:439.1 *et seq.*; Md. Code Ann., Health-Gen. § 2-601 *et seq.*; Mass. Gen. Laws ch. 12, § 5A *et seq.*; Mich. Comp. Laws § 400.601 *et seq.*; Minn. Stat. § 15C.01 *et seq.*; Mont. Code Ann. § 17-8-401 *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.J. Stat. Ann. § 2A:32C-1 *et seq.*; N.M. Stat. Ann. § 27-14-1 *et seq.*; N.Y. State Fin. Law § 187 *et seq.*; N.C. Gen. Stat. § 1-605 *et seq.*; Okla. Stat. tit. 63, § 5053 *et seq.*; R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.*; and Wis. Stat. § 20.931 *et seq.*

B. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a),

plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and Cal. Gov't Code § 12652(g)(4), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. § 17b-301e(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Va. Code Ann. § 8.01-216.7, and Wis. Stat. § 20.931(11), including without limitation (i) reinstatement of Relator Weathersby's employment with no diminution of seniority, (ii) double back-pay for the period since Relator Weathersby's unlawful retaliatory termination, (iii) interest on such back-pay for Relator Weathersby, and (iv) special damages to Relators, including reasonable attorneys' fees and litigation costs.

D. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by

Cal. Gov't Code § 12651(a), to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500)

or more than eleven thousand dollars ($11,000) for each act in violation of the Delaware False Claims and Reporting Act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168(a), plus a civil penalty of not less than five thousand

five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim as provided by Ga. Code Ann. § 49-4-168(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) as provided by Ind. Code

§ 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6(B)(1), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such

penalties fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relators' favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than five thousand dollars ($5,000) dollars and not more than ten thousand dollars ($10,000), plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch 12. § 5B, to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relators, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relators, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mont. Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act, pursuant to Nev. Rev.

Stat. § 357.040(1), to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*) for each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relators' favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relators' favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars

($12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relators' favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. Gen. Stat. § 1-607, multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Okla. Stat. tit. 63, § 5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as

provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by R.I. Gen. Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) pursuant to Tenn. Code Ann. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in

injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in Wis. Stat. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Wis. Stat. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

FF. That judgment be granted for Relators against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit; and

GG. That Relators be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Relators demand a trial by jury of all issues so triable.

Dated: December 21, 2011

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